CareSource Pharmacy Policy Statement
Marketplace
Kalbitor

Drug Name: Kalbitor (ecallantide)
Billing Code: J1290
Benefit Type: Medical
Site of Service Allowed: Home/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Berinert and Firazyr
Quantity Limit: 6 mL per fill (18 mL per 30 days)

Kalbitor (ecallantide) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:
1. Member must be 12 years of age or older, and medication is being used **for the treatment of acute HAE attacks** (NOT for treatment of acquired angioedema); AND
2. Medication must be prescribed by or in consultation with a provider specializing in allergy, immunology, or hematology; AND
3. Member has documented trial and failure of or contraindication to **both** Firazyr and Berinert (Chart notes required); AND
4. Member must have a confirmed diagnosis of HAE as **one** of the following:
   a) Type 1 HAE documented in chart notes with ALL of the following (*Note:* tests listed below must be repeated for confirmation of diagnosis):
      i) Low levels (below the limits of the laboratory's normal reference range) of C4, C1-INH antigenic protein and C1-INH functional level; AND
      ii) Positive family history of angioedema OR earlier age of onset (before age 30) with normal C1q antigenic protein level;
   b) Type 2 HAE documented in chart notes with ALL of the following (*Note:* tests listed below must be repeated for confirmation of diagnosis):
      i) Normal or elevated level of C1-INH antigenic protein (as defined by performing lab); AND
      ii) Low level (below the limits of the laboratory's normal reference range) C4 and C1-INH functional; AND
5. Medication is **not** being used in combination with Berinert, Firazyr, or Ruconest; AND
6. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.
7. **Dosage allowed:** Three 10 mg (1mL) injection at onset; repeat within 24 hours if the attack persists.

Note: *Personal documentation (log book, journal, etc.) of medication use will be necessary for reauthorization. Prescribers should be aware and make their patients aware of this requirement for reauthorization.*

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND

2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
3. Log of medication use supported by medical chart or by claims data has been provided.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Kalbitor (ecallantide) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acquired angioedema (AAE)
- HAE prophylactic therapy

References:

1. Kalbitor [package insert]. Burlington, MA; Dyax Corp.; September 2014.
2. Cicardi M, Zuraw B, Saini S, et al. Hereditary angioedema: pathogenesis and diagnosis. UpToDate. Updated November 15, 2016.
3. Craig, T., Pürsün, E. A., Bork, K., Bowen, et al. (2012). WAO Guideline for the Management of Hereditary Angioedema. The World Allergy Organization Journal, 5(12), 182–199. http://doi.org/10.1097/WOX.0b013e318279affa.
4. Frank MM, Zuraw B, Banerji A, et al. Management of children with hereditary angioedema due to C1 inhibitor deficiency. Pediatrics. 2016 Nov;138(5). pii: e20160575.
5. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. Allergy Asthma Clin Immunol. 2010;6(1):24.
6. Kalbitor. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed August 8, 2017.

Effective date: 11/01/2019
Revised date: 08/28/2017

Update record:
11/12/2019 New Marketplace policy for Kalbitor created

CareSource Pharmacy Policy Statement
Marketplace
Kanuma

Drug Name: Kanuma (sebelipase alfa)
Billing Code: J2840
Benefit Type: Medical
Site of Service Allowed: Outpatient/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: Up to 3 mg/kg once weekly

Kanuma (sebelipase alfa) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY

For **initial** authorization:
1. Member has lab confirmed diagnosis of LAL deficiency; AND
2. Medication must be prescribed by endocrinologist, cardiologist, or hepatologist or other or other specialist in the area of the member's disease; AND
3. Member is > 8 months but < 4 years of age with at least **one** of the following documented clinical manifestations of LALD:
   a) Dyslipidemia;
   b) Elevated transaminases (ALT ≥1.5x ULN);
   c) Impaired growth;
   d) Suspected malabsorption;
   e) Other clinical manifestation of LALD; OR
4. Member is ≥ 4 years of age with at least **one** of the following documented clinical manifestations of LALD:
   a) Evidence of advanced liver disease;
   b) Histologically confirmed disease recurrence in members with past liver or hematopoietic transplant;
   c) Persistent dyslipidemia;
   d) Suspected malabsorption;
   e) Other clinical manifestation of LALD.
5. **Dosage allowed:** 1 mg/kg administered once weekly as an IV infusion. For members with rapidly progressive LAL deficiency presenting within the first 6 months of life and who do not achieve an optimal clinical response, increase to 3 mg/kg once weekly.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Kanuma (sebelipase alfa) not medically necessary for the treatment of the diseases that are not listed in this document.

CareSource Pharmacy Policy Statement
Marketplace
Kanuma

References:
1. Kanuma [package inset]. New Haven, CT: Alexion Pharmaceuticals Inc.; December, 2015.
2. linicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT02112994. Safety and Efficacy Study of Sebelipase Alfa in Patients With Lysosomal Acid Lipase Deficiency. February 14, 2018. Available at: https://clinicaltrials.gov/ct2/show/NCT02112994?term=sebelipase+alfa&recrs=e&rank=1.
3. Hoffman EP, et al. Lysosomal acid lipase deficiency. In: ed. Adam MP, et al. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. 2015 Jul 30 [Updated 2016 Sep 1].
4. Desai NK, et al. Lysosomal acid lipase deficiency. In: ed. De Groot LJ, et al. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000-. [Updated 2016 Jun 22].

Effective date: 11/01/2019
Revised date: 04/11/2018

Update record:
11/12/2019 New Marketplace policy for Kanuma created

CareSource Pharmacy Policy Statement
Marketplace
Kymriah

Drug Name: Kymriah (tisangenlecleucel)
Billing Code: Q2040 (1 unit = 250 million T cells)
Benefit Type: Medical
Site of Service Allowed: Outpatient/Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: See Dosage allowed below

Kymriah (tisagenlecleucel) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) – for autologous use only

For **initial** authorization:

1. Member is 3-25 years of age and has documentation of CD19 tumor expression; AND
2. Member has B-cell acute lymphoblastic leukemia that is refractory or in second or later relapse as defined by **one** of the following:
   a) 2nd or greater Bone Marrow (BM) relapse;
   b) Any BM relapse after allogeneic stem cell transplantation (SCT) and must be > 6 months from SCT at the time of CAR-T cell immunotherapy infusion;
   c) Refractory as defined by not achieving a complete remission (CR) after 2 cycles of a standard chemotherapy regimen chemotherapy regimen or chemorefractory as defined by not achieving a CR after 1 cycle of standard chemotherapy for relapse leukemia;
   d) Member with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia that is intolerant to or have failed 2 lines of tyrosine kinase inhibitor (TKI) therapy (e.g. imatinib mesylate (Gleevec), dasatinib (Sprycel), nilotinib (Tasigna) or ponatinib (Iclusig)), or if TKI therapy is contraindicated;
   e) Member is not eligible for allogeneic SCT; AND
3. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (leukapheresis); AND
4. Healthcare facility/provider has enrolled in the Kymriah REMS and has training on the management of cytokine release syndrome (CRS) and neurological toxicities; AND
5. Member must be premedicated with acetaminophen and an H1-antihistamine, and tocilizumab (Actemra) must be available in healthcare facility prior to infusion; AND
6. Member has a life expectancy > 12 weeks; AND
7. Member does **not** have history of ALL of the following:
   a) Prior CAR-T therapy;
   b) Concomitant genetic syndrome (e.g., Fanconi anemia, Kostmann syndrome, Shwachman syndrome or any other known bone marrow failure syndrome);
   c) Burkitt's lymphoma/leukemia;
   d) Malignancy, except carcinoma in situ of the skin or cervix treated with curative intent and with no evidence of active disease;
   e) Prior treatment with gene therapy product;
   f) Presence of Grade 2 to 4 acute or extensive chronic graft-versus-host disease (GVHD);
   g) Active or latent hepatitis B or active hepatitis C or HIV.

8. **Dosage allowed:** Weight 50 kg or less: administer 0.2 to 5.0 x 10^6CAR-positive viable T cells per kg body weight intravenously. Weight above 50 kg: administer 0.1 to 2.5 x 10^8 total CAR-positive viable T cells (non-weight based) intravenously.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
Kymriah will not be reauthorized for continued therapy.

LARGE B-CELL LYMPHOMA – for autologous use only

For **initial** authorization:
1. Member is being use for adult member (18 years old or older) with has relapsed or refractory large B-cell lymphoma (diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma); AND
2. Member has received ≥ 2 lines of chemotherapy, including rituximab and anthracycline, or relapsed following autologous hematopoietic stem cell transplantation (HSCT); AND
3. Member does **not** have ALL of the following:
   a) Active central nervous system malignancy;
   b) Prior allogenic HSCT;
   c) ECOG performance status ≥ 2;
   d) Creatinine clearance < 60;
   e) Alanine aminotransferase > 5 times normal;
   f) Cardiac ejection fraction < 45%;
   g) Absolute lymphocyte concentration less than 300/μL;
   h) Active replication of or prior infection with hepatitis B or active hepatitis C (HCV RNA positive);
   i) HIV positive; AND
4. Healthcare facility/provider has enrolled in the Kymriah REMS and has training on the management of cytokine release syndrome (CRS) and neurological toxicities; AND
5. Member must be premedicated with acetaminophen and an H1-antihistamine, and tocilizumab (Actemra) must be available in healthcare facility prior to infusion; AND
6. Member has a life expectancy > 12 weeks; AND
7. Member has not received prior CAR-T therapy.
8. **Dosage allowed:** Administer 0.6 to 6.0 x 10^8 CAR-positive viable T cells.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Kymriah will not be reauthorized for continued therapy.

CareSource considers Kymriah (tisagenlecleucel) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Primary central nervous system lymphoma

CareSource Pharmacy Policy Statement
Marketplace
Kymriah

References:

1. Kymriah [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corp., May 2018.
2. The Leukemia & Lymphoma Society (LLS). Ph-Positive ALL Therapy. Available at https://www.lls.org/leukemia/acute-lymphoblastic-leukemia/treatment/ph-positive-all-therapy.
3. ClinicalTrials.gov. Identifier NCT02228096. Study of Efficacy and Safety of CTL019 in Pediatric ALL Patients. Available at https://clinicaltrials.gov/ct2/show/NCT02228096?term=tisagenlecleucel&rank=1. Accessed in October, 2017.
4. Maude SL, et al. Tisagenlecleucel in Children and Young Adults with B-Cell Lymphoblastic Leukemia. N Engl J Med. 2018;378(5):439-448. [PubMed 29385370]
5. Schuster SJ, et al. Primary analysis of Juliet: a global, pivotal, phase 2 trial of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma. Blood. 2017;130(s1):577 [Abstract 577 from 2017 ASH annual meeting].
6. NCCN Guidelines. Acute Lymphoblastic Leukemia. V.1.2018
7. NCCN Guidelines. Non-Hodgkins Lymphoma. V.4.2018.

Effective date: 11/01/2019
Revised date: 08/27/2018

Update record:
11/12/2019 New Marketplace policy for Kymriah created

CareSource Pharmacy Policy Statement
Marketplace
Lemtrada

Drug Name: Lemtrada (alemtuzumab)
Billing Code: J0202
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: 60 mg

Lemtrada (alemtuzumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS), SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

For **initial** authorization:
1. Member must be 17 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Chart notes have been provided confirming diagnosis of Multiple Sclerosis; AND
4. Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug).
5. **Dosage allowed:** Initial course 12 mg per day for 5 consecutive days (60 mg total dose).

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Doses of Lemtrada separated by at least 12 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Lemtrada (alemtuzumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis
- Autoimmune disease
- Chronic lymphoid leukemia
- Malignant tumor of lymphoid hemopoietic and related tissue
- Primary cutaneous T-cell lymphoma, Relapsed or refractory
- Renal transplant rejection, Induction therapy; Prophylaxis
- T-cell prolymphocytic leukemia

CareSource Pharmacy Policy Statement
Marketplace
Lemtrada

References:

1. Lemtrada [package insert]. Cambridge, MA; Genzyme, Inc: June, 2016.
2. Lemtrada. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed April 7, 2017.
3. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan;58(2):169-78.
4. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Annals of Neurology. 2011;69(2):292-302. doi:10.1002/ana.22366.

Effective date: 11/01/2019
Revised date: 12/06/2017

Update record:
11/12/2019 New Marketplace policy for Lemtrada created

CareSource Pharmacy Policy Statement
Marketplace
Lupron

Drug Name: Lupron Depot and Lupron Depot-PED (leuprolide acetate)
Billing Code: J1950, J9217, J9218
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: See "**Dosage allowed**" below

Lupron Depot and Lupron Depot-PED (leuprolide acetate) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ADVANCED BREAST CANCER

For **initial** authorization:
1. Member is pre- OR peri-menopausal women with locally advanced, recurrent, or metastatic hormone receptor-positive breast cancer; AND
2. Member is not currently breast feeding, pregnant, or planning to become pregnant while receiving medication; AND
3. Medication must be prescribed by oncologist, gynecologist or obstetrician.
4. **Dosage allowed:** Lupron Depot 3.75 mg for 1-month or 11.25 mg for 3-month administration.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CENTRAL PRECOCIOUS PUBERTY (CPP)

For **initial** authorization:
1. Pubertal symptoms appeared before the age of 9 in male member or before the age of 8 in female member; AND
2. Member has confirmed diagnostic evaluation, including assessment of **one** of the following:
   a) Bone age advanced one year beyond chronological age;
   b) Pubertal response to a gonadotropin releasing hormone (GnRH) stimulation test; AND
3. Member's baseline gonadal sex steroid hormone levels, adrenal steroid levels, height and weight are submitted with chart notes; AND
4. Other diagnosis are ruled out (e.g., intracranial tumors, congenital adrenal hyperplasia, chronic gonadotropin-secreting tumor, etc.); AND
5. Female member must meet ALL of the following:
   a) Breast development Tanner stage 2 or greater;
   b) Menstrual bleeding or vaginal discharge;
   c) No pregnancy currently;

   d) No undiagnosed abnormal vaginal bleeding; OR
6. Male member must meet ALL of the following:
   a) Signs and symptoms as indicated by **one** or more of the following:
      i) Acne;
      ii) Erections;
      iii) Nocturnal emissions;
      iv) Oily skin; AND
   b) Testicular volume 4 mL or greater.
7. **Dosage allowed:** Lupron Depot-PED - Single intramuscular injection. The starting dose 7.5 mg, 11.25 mg, or 15 mg for 1-month administration is based on the child's weight. The doses are either 11.25 mg or 30 mg for 3-month administration.

Note: Discontinuation of leuprolide for central precocious puberty should be considered at age 11 for girls and age 12 for boys.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

ENDOMETRIOSIS

For **initial** authorization:
1. Member is a female of 18 years of age or older; AND
2. Member is not currently breast feeding, pregnant, or planning to become pregnant while receiving medication; AND
3. Medication must be prescribed by gynecologist or obstetrician; AND
4. Medication must be prescribed with daily norethindrone acetate 5 mg (Leuprolide Depot alone is not recommended for retreatment. If norethindrone acetate is contraindicated, then retreatment is not recommended); AND
5. Endometriosis symptoms, as indicated by **one** or more of the following:
   a) Dysmenorrhea;
   b) Dyspareunia;
   c) Pelvic pain; AND
6. Member has failed control of symptoms with ALL of the following:
   a) NSAIDs;
   b) Any contraceptives.
7. **Dosage allowed:** Lupron Depot 3.75 mg for 1-month or 11.25 mg for 3-month administration.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Leuprolide Depot alone is not recommended for retreatment. If norethindrone acetate is contraindicated, then retreatment is not recommended.

CareSource Pharmacy Policy Statement
Marketplace
Lupron

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

ADVANCED PROSTATE CANCER (Palliative Treatment)

For **initial** authorization:
1. Member has signs and symptoms of symptomatic locally advanced, recurrent, or metastatic disease; AND
2. Member has intermediate to high risk of disease recurrence in clinically localized prostate cancer, as indicated by **one** or more of the following:
   a) Intermediate risk of recurrence:
      i) T2a or lower, an aggressive histologic pattern (i.e., Gleason score of 7);
      ii) T2a or lower, and PSA 10 to 20mg/mL (mcg/L);
      iii) T2b or T2c;
   b) High risk of recurrence:
      i) T2c or lower, and aggressive histologic pattern (i.e., Gleason score of 8 to 10);
      ii) T2c or lower, and PSA greater than 20 ng/mL (mcg/L);
      iii) T3a; AND
3. Medication must be prescribed by urologist or oncologist.
4. **Dosage allowed:** Lupron Depot 7.5 mg for 1-month administration, given as a single intramuscular injection every 4 weeks. Lupron Depot 22.5 mg for 3-month administration, given as a single intramuscular injection every 12 weeks. Lupron Depot 30 mg for 4-month administration, given as a single intramuscular injection every 16 weeks. Lupron Depot 45 mg for 6-month administration, given as a single intramuscular injection every 24 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease or member did not get any worse.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

UTERINE LEIOMYOMAS (FIBROIDS)

For **initial** authorization:
1. Member is a female of 18 years of age or older; AND
2. Member is not currently breast feeding, pregnant, or planning to become pregnant while receiving medication; AND
3. Medication must be prescribed by gynecologist or obstetrician; AND
4. Proposed date of planned fibroid surgery submitted with chart notes; AND
5. Leiomyoma symptoms, as indicated by **one** or more of the following:
   a) Abnormal uterine bleeding;
   b) Bulk-related symptoms (e.g., pelvic pain or pressure, dyspareunia, urinary symptoms);
   c) Iron deficiency anemia;
   d) Other causes of symptoms or bleeding ruled out (e.g., by endometrial biopsy).
6. **Dosage allowed:** Lupron Depot 3.75 mg for 1-month and 11.25 mg for 3-month administration with iron therapy are prescription medications used before fibroid surgery to improve anemia due to vaginal bleeding from fibroids.

CareSource Pharmacy Policy Statement
Marketplace
Lupron

Note: Treatment beyond total of 3 months is considered unproven, therefore second reauthorization would not be allowed.

If member meets all the requirements listed above, the medication will be approved for 3 months.

CareSource considers Lupron Depot and Lupron Depot-PED (leuprolide acetate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Dysfunctional Uterine Bleeding

References:

1. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; June, 2016.
2. Lupron Depot – PED [package insert]. North Chicago, IL: AbbVie Inc.; May, 2017.
3. Burstein HJ, Lacchetti C, Anderson H, et al. Adjuvant endocrine therapy for women with hormone receptor-positive breast cancer: American society of clinical oncology clinical practice guideline update on ovarian suppression. *J Clin Oncol*. 2016;34(14):1689-701.
4. Dowsett M, Mehta A, Mansi J, Smith IE. A dose-comparative endocrine-clinical study of leuprorelin in premenopausal breast cancer patients. Br J Cancer. 1990;62(5):834-837.
5. Dowsett M, Jacobs S, Aherne J, Smith IE. Clinical and endocrine effects on leuprorelin acetate in pre- and postmenopausal patients with advanced breast cancer. *Clin Ther*. 1992;14(suppl A):97-103.
6. Gradishar WJ, Anderson BO, Blair SL, et al, and the National Comprehensive Cancer Network Breast Cancer Panel. Breast cancer version 3.2014. J Natl Compr Canc Netw. 2014;12(4):542-590.
7. Kurebayashi J, Toyama T, Sumino S, Miyajima E, Fujimoto T. Efficacy and safety of leuprorelin acetate 6-month depot, TAP-144-SR (6M), in combination with tamoxifen in postoperative, premenopausal patients with hormone receptor-positive breast cancer: A phase III, randomized, open-label, parallel-group comparative study. *Breast Cancer*. 2017;24(1):161-170.
8. Recchia F, Candeloro G, Necozione S, et al. Premenopausal hormone-responsive breast cancer with extensive axillary nodes involvement: total estrogen blockade and chemotherapy. *Anticancer Res.* 2011;31:671-676.
9. Schmid P, Untch M, Kossé V, et al. Leuprorelin acetate every-3-months depot versus cyclophosphamide, methotrexate, and fluorouracil as adjuvant treatment in premenopausal patients with node-positive breast cancer: the TABLE study. *J Clin Oncol*. 2007;25(18):2509-2515.
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11. Untch M, Fuchs W, Kreienberg R. Clinical efficacy of leuprorelin acetate monthly depot in premenopausal patients with metastatic breast cancer. *Oncol Rep*. 1997;4(4):717-721.
12. Watanabe T, Adachi I, Taguchi T, et al; with members of the TAP-144-SR Breast Cancer Study Group. Phase II trial of TAP-144-SR (leuprorelin sustained release formulation) in premenopausal patients with metastatic breast cancer (MBC) [abstract]. Breast Cancer Res Treat. 1996;37(suppl 1):74. Abstract 233.
13. Jasonni VM, D'Anna R, Mancuso A, Caruso C, Corrado F, Leonardi I. Randomized double-blind study evaluating the efficacy on uterine fibroids shrinkage and on intra-operative blood loss of different length of leuprolide acetate depot treatment before myomectomy. *Acta Obstet Gynecol Scand*. 2001;80(10):956-958.
14. Palomba S, Orio Jr. F, Russo T, et al. Long-term effectiveness and safety of GnRH agonist plus raloxifene administration in women with uterine leiomyomas. *Human Reproduction*. 2004;19(6):1308-1314.
15. Schlaff WD, Zerhouni EA, Huth JAM, Chen J, Damewood MD, Rock JA. A placebo-controlled trial of a depot gonadotropin-releasing hormone analogue (leuprolide) in the treatment of uterine leiomyomata. *Obstet Gynecol*. 1989;74(6):856-862.

16. Vavalà V, Lanzone A, Monaco A, Scribanti A, Guida C, Mancuso S. Postoperative GnRH analog treatment for the prevention of recurrences of uterine myomas after myomectomy. A pilot study. Gynecol Obstet Invest. 1997;43(4):251-254.
17. Stovall TG, Muneyyirci-Delale O, Summitt RL Jr, Scialli AR; Leuprolide Acetate Study Group. GnRH agonist and iron versus placebo and iron in the anemic patient before surgery for leiomyomas: a randomized controlled trial. *Obstet Gynecol*. 1995;86(1):65-71.
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19. Mitwally MFM, Gotlieb L, Casper RF. Prevention of bone loss and hypoestrogenic symptoms by estrogen and interrupted progestogen add-back in long-term GnRH-agonist down-regulated patients with endometriosis and premenstrual syndrome. Menopause. 2002;9(4):236-241.
20. Bedaiwy MA, Casper RF. Treatment with leuprolide acetate and hormonal add-back for up to 10 years in stage IV endometriosis patients with chronic pelvic pain [letter]. Fertil Steril. 2006;86(1):220-222.
21. Eksioglu AS, et al. Value of pelvic sonography in the diagnosis of various forms of precocious puberty in girls. J *Clin Ultrasound*. 2013 Feb;41(2):84-93.
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Effective date: 11/01/2019
Revised date: 10/09/2018

Update record:
11/12/2019 New Marketplace policy for Lupron created

CareSource Pharmacy Policy Statement
Marketplace
Luxturna

Drug Name: Luxturna (voretigene neparvovec-rzyl) intraocular suspension for subretinal injection
Billing Code: C9032
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: 1 Luxturna carton per eye for lifetime

Luxturna (voretigene neparvovec-rzyl) intraocular suspension for subretinal injection is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

BIALLELIC RPE65 MUTATION-ASSOCIATED RETINAL DYSTROPHY

For **initial** authorization:
1. Member is 3 years of age or older; AND
2. Medication must be prescribed by ophthalmologist or retinal surgeon; AND
3. Member has confirmed diagnosis of biallelic RPE65 mutation-associated retinal dystrophy by genetic testing in a CLIA-certified laboratory; AND
4. Member has baseline multi-luminance mobility testing (MLMT) score documented in chart notes; AND
5. Member has sufficient viable retinal cells as determined by retinal thickness on spectral domain optical coherence tomography (>100 microns within the posterior pole); AND
6. Member's visual acuity is 20/60 or worse (both eyes) and/or visual field less than 20 degrees in any meridian as measured by a III4e isopter or equivalent (both eyes); AND
7. Member was not previously treated with RPE65 gene therapy.
8. **Dosage allowed:** 1.5×10^{11} vector genomes (vg), administered by subretinal injection in a total volume of 0.3 mL for each eye. Administration of Luxturna to each eye must be performed on separate days within a close interval, but not fewer than 6 days.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Medication will not be reauthorization for continuous use.

CareSource considers Luxturna (voretigene neparvovec-rzyl) intraocular suspension for subretinal injection not medically necessary for the treatment of the diseases that are not listed in this document.

References:

1. Luxturna [package insert]. Philadelphia, PA; Spark Therapeutics, Inc.: 2017.
2. Maguire AM, Simonelli F, Pierce EA, at el. Safety and efficacy of gene transfer for Leber's congenital amaurosis. N Engl J Med. 2008 May 22;358(21):2240-8. doi: 10.1056/NEJMoa0802315. Epub 2008 Apr 27.
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Effective date: 11/01/2019
Revised date: 08/27/2018

Update record:
11/12/2019 New Marketplace policy for Luxturna created

CareSource Pharmacy Policy Statement
Marketplace
Mepsevii

Drug Name: Mepsevii (vestronidase alfa-vjbk)
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: 4 mg/kg every two weeks

Mepsevii (vestronidase alfa-vjbk) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

SLY SYNDROME (Mucopolysaccharidosis VII or MPS VII)

For **initial** authorization:
1. Member has documented leukocyte or fibroblast glucuronidase enzyme assay or genetic testing confirming diagnosis of MPS VII; AND
2. Member did **not** undergo a successful bone marrow or stem cell transplant or has any degree of detectable chimaerism with donor cells; AND
3. Member has elevated urinary glycosaminoglycan (uGAG) excretion at a minimum of 2-fold over the mean normal for age; AND
4. Member's chart notes have baseline of at least **two** of the following: six-minute walk test (6MWT), Forced Vital Capacity (FVC), shoulder flexion, visual acuity, and Bruininks-Oseretsky Test of Motor Proficiency (BOT-2) (fine motor and gross motor skills).
5. **Dosage allowed:** 4 mg/kg administered by intravenous infusion every two weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided that show the member has shown improvement from baseline of any of the following: six-minute walk test (6MWT), forced vital capacity, motor function, visual acuity, or liver and spleen volume.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Mepsevii (vestronidase alfa-vjbk) not medically necessary for the treatment of the diseases that are not listed in this document.

References:
1. Mepsevii [package insert]. Novato, CA: Ultragenyx Pharmaceutical Inc.; November, 2017.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT01856218. An Open-Label Phase 1/2 Study to Assess the Safety, Efficacy and Dose of Study Drug UX003 Recombinant Human Beta-glucuronidase (rhGUS) Enzyme Replacement Therapy in Patients With Mucopolysaccharidosis Type 7 (MPS 7); January 31, 2018. Available at: https://clinicaltrials.gov/ct2/show/NCT01856218?term=NCT01856218&rank=1.
3. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT02230566. A Phase 3 Study of UX003 Recombinant Human Betaglucuronidase (rhGUS) Enzyme Replacement Therapy in Patients

With Mucopolysaccharidosis Type 7 (MPS 7); February 16, 2018. Available at: https://clinicaltrials.gov/ct2/show/NCT02230566?term=NCT02230566&rank=1.

4. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT02432144. A Long-Term Open-Label Treatment and Extension Study of UX003 rhGUS Enzyme Replacement Therapy in Subjects With MPS 7; November 6, 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT02432144?term=NCT02432144&rank=1.
5. Harmatz P, et al. A novel Blind Start study design to investigate vestronidase alfa for mucopolysaccharidosis VII, an ultra-rare genetic disease. Mol Genet Metab. 2018 Apr;123(4):488-494.

Effective date: 11/01/2019
Revised date: 09/13/2018

Update record:
11/12/2019 New Marketplace policy for Mepsevii created

CareSource Pharmacy Policy Statement
Marketplace
Monovisc

Drug Name: Monovisc (sodium hyaluronate)
Billing Code: J7327
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Durolane, Supartz FX, Gelsyn-3
Quantity Limit: 1 injection (1 unit)

Monovisc (sodium hyaluronate) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OSTEOARTHRITIS OF THE KNEE

For **initial** authorization:
1. Member must be 40 years old or older; AND
2. Member must have a diagnosis of osteoarthritis confirmed by radiological evidence (e.g. Kellgren-Lawrence Scale score of grade 2 or greater); AND
3. Medication must be prescribed by an orthopedic surgeon, interventional pain physicians, rheumatologists, physiatrists (PM&R) and all sports medicine subspecialties; AND
4. Member tried and failed an intra-articular corticosteroid injection(s) in which efficacy was < 4 weeks duration; AND
5. Documentation that member tried and failed ALL of the following:
   a) Weight loss attempts or attempts at lifestyle modifications to promote weight loss (only for members with BMI ≥30); AND
   b) Sufficient trial (e.g. 2 to 3 months) of non-pharmacologic therapies (bracing/orthotics, physical/occupational therapy); AND
   c) At least 3 simple analgesic therapies (acetaminophen, NSAIDs, oral or topical salicylates); AND
6. Member is not using medication for hip or shoulder related conditions; AND
7. Member has tried and failed to respond to treatment with Supartz FX or Durolane or Gelsyn-3 (documented in chart notes and confirmed by claims history).
8. **Dosage allowed:** Inject 88 mg (4 mL) once.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must have documented significant pain relief that was achieved with the initial course of treatment; AND
2. Initial course of treatment has been completed for 6 months or longer; AND
3. Member meets all of the criteria for the initial approval.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Monovisc (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust

CareSource Pharmacy Policy Statement
Marketplace
Monovisc

clinical controlled trials showing superior efficacy compared to currently available treatments:

- Refractory interstitial cystitis
- Arthropathy – Disorder of shoulder
- Intravitreal tamponade
- Keratoconjunctivitis sicca
- Subacromial impingement, Syndrome of the shoulder

References:

1. Monovisc [package insert]. Bedford, MA; Anika Therapuetics; 2013.
2. American Academy of Orthopaedic Surgeons. Treatment of Osteoarthritis of the Knee. Evidence-based guideline 2nd Edition. May 2013. Available at: http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf (December 31, 2015).
3. American College of Rheumatology, Subcommittee on Osteoarthritis Guidelines. Recommendations for the medical management of osteoarthritis of the hip and knee: 2012 update. Arthritis Care & Research 2012; 64(4):465-474. Agency for Healthcare Research and Quality (AHRQ). Three Treatments for Osteoarthritis of the Knee: Evidence Shows Lack of Benefit. Clinician's Guide. March, 2011.
4. Goldberg VM, Buckwater MD. Hyaluronans in the treatment of osteoarthritis of the knee: evidence for disease modifying activity. Osteoarthritis and Cartilage March 2005;13(3):216-224.
5. Majeed M. Relationship between serum hyaluronic acid level and disease activity in early rheumatoid arthritis. Ann Rheum Dis September 2004; 63(9): 1166-8.
6. Tascioglu F, Oner C. Efficacy of intra-articular sodium hyaluronate in the treatment of knee osteoarthritis. Clini Rheumatol. 2003;22:112-117.
7. Lo, G H, et al. JAMA. 2003;290:3115-3121. Intra-articular Hyaluronic Acid in Treatment of Knee Osteoarthritis: A Meta- analysis. Retrieved 3/17/2011 from http://jama.ama-assn.org/cgi/reprint/290/23/3115.
8. Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Viscosupplementation for the treatment of osteoarthritis of the knee. Cochrane Database Syst Rev. 2006;(2):CD005321.
9. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. Clin Orthop Relat Res. 2007; 455:113-22.
10. Monovisc. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 17, 2017.
11. Monovisc. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed May 17, 2017.
12. McGrath AF, McGrath AM, Jessop ZM, et al. A comparison of intra-articular hyaluronic acid competitors in the treatment of mild to moderate knee osteoarthritis. J Arthritis. 2013; 2(1):108. doi:10.4172/2167-7921.1000108.
13. Leighton R, Åkermark C, Therrien R, et. al. NASHA hyaluronic acid vs methylprednisolone for knee osteoarthritis: a prospective, multi-centre, randomized, non-inferiority trial. Osteoarthritis Cartilage. 2014; 22(1):17-25.

Effective date: 11/01/2019
Revised date: 11/05/2019

Update record:
11/12/2019 New Marketplace policy for Monovisc created

CareSource Pharmacy Policy Statement
Marketplace
Myobloc

Drug Name: Myobloc (rimabotulinumtoxinB)
Billing Code: J0587
Benefit Type: Medical
Site of Service Allowed: Office, Outpatient
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: Up to 5,000 Units per treatment

Myobloc (rimabotulinumtoxinB) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

For **initial** authorization:
1. Member has a pain or abnormal head position with documented turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis) causing adverse effect on daily functioning; AND
2. Member has tried and failed one oral medication such as trihexyphenidyl (Artane), clonazepam (Klonopin), or baclofen; AND
3. Member does **not** have any of the following:
   a) Fixed contractures causing decreased neck range of motion;
   b) Neuromuscular disease (e.g., myasthenia gravis);
   c) Prior surgical treatment.
4. **Dosage allowed:** 2,500 to 5,000 Units divided among affected muscles.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Myobloc (rimabotulinumtoxinB) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Tension headache, cervicogenic headache
- Myofascial pain syndrome
- Tremors such as benign essential tremor, chronic motor tic disorder and tics associated with Tourette Syndrome
- Parkinson's disease

CareSource Pharmacy Policy Statement
Marketplace
Myobloc

- Sialorrhea due to Parkinson's disease

References:

1. Myobloc [package insert].San Francisco, CA: Solstice Neurosciences, Inc.; July 2009.
2. MCG 20th Edition, 2016.
3. U.S. Drug and Food Administration Safety Data. http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/125036s044lbl.pdf (March 6, 2011).
4. Wolters Kluwer. Facts &Comparisons. www.factsandcomparisons.com, 2011. (March 6, 2011).
5. Brashear A, Lew MF, Dykstra DD, et al, “Safety and Efficacy of NeuroBloc (Botulinum Toxin Type B) in Type A-Responsive Cervical Dystonia,” Neurology, 1999, 53(7):1439-46.
6. Clinical Use of Botulinum Toxin,” Arch Neurol, 1991, 48(12):1294-8.
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9. Naumann M and Jankovic J, "Safety of Botulinum Toxin Type A: A Systematic Review and Meta-Analysis," Curr Med Res Opin, 2004, 20(7):981-90.
10. Russman, BS, Tilton, A, Gormley ME. Jr. Cerebral palsy; a rational approach to a treatment protocol, and the role of botulinum toxin in treatment, Muscle Nerve Suppl 1997; 6:S181.
11. Fishman LM, Anderson C, Rosner B. Botox and physical therapy in the treatment of Piriformis syndrome Am J Phys Med Rehabil. 2002 Dec;81(12):936-42.
12. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academyof Neurology. http://www.guideline.gov/content.aspx?id=12942(March112011).
13. Simpson DM, et al. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. Neurology. 2008;70(19):1699-706.
14. Neumann M, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain. Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. Neurology. 2008; 70:1707-14.
15. Keam SJ, Muir VJ, Deeks ED. Botulinum toxin A (Dysport): in dystonias and focal spasticity. Drugs 2011;71(8):1043-58.
16. Ondo WG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson’s disease. Neurology. 2004;62(1):37-40.

Effective date: 11/01/2019
Revised date: 08/06/2018

Update record:
11/12/2019 New Marketplace policy for Myobloc created

CareSource Pharmacy Policy Statement
Marketplace
Novantrone

Drug Name: Novantrone (mitoxantrone)
Billing Code: J9293 (1 unit = 5 mg)
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: 5 units per infusion

Novantrone (mitoxantrone) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS), SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Chart notes have been provided confirming diagnosis of Multiple Sclerosis; AND
4. Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug); AND
5. Member has documented Left Ventricular Ejection Fraction (LVEF) of greater than 50% in the chart notes within the last 3 months.
6. **Dosage allowed:** 12 mg/m^2 infusion every 3 months (Maximum cumulative lifetime dose is 140 mg/m^2).

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Member has documented biological response to treatment; AND
3. Member has documentation of repeated Left ventricular ejection fraction (LVEF) of greater than 50% in the chart notes (Note: Maximum cumulative lifetime dose is 140 mg/m^2).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Novantrone (mitoxantrone) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acute lymphoid leukemia
- Bone marrow transplant
- Breast cancer
- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis
- Head and neck cancer

CareSource Pharmacy Policy Statement
Marketplace
Novantrone

- Liver carcinoma
- Malignant lymphoma, Indolent
- Non-Hodgkin's lymphoma
- Ovarian cancer
- Primary progressive multiple sclerosis
- Solid tumor

References:

1. Mitoxantrone [package insert]. Lake Zurich, IL; Fresenius Kabi USA, LLC: June, 2015.
2. Mitoxantrone. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 16, 2017.
3. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan;58(2):169-78.
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Effective date: 11/01/2019
Revised date: 12/06/2017

Update record:
11/12/2019 New Marketplace policy for Novantrone created

CareSource Pharmacy Policy Statement
Marketplace
NPlate

Drug Name: NPlate (romiplostim)
Billing Code: J2796
Benefit Type: Medical
Site of Service Allowed: Hospital, Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include immune globulins and Promacta
Quantity Limit: 10 mcg/kg (actual body weight)

NPlate (romiplostim) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

IMMUNE THROMBOCYTOPENIC PURPURA (ITP)

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Member has a documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND
3. Medication must be prescribed by or in consultation with a hematologist; AND
4. Member has ONE of the following conditions:
   a) Current platelet count is $<30x10^9$/L;
   b) $30x10^9$/L to $50x10^9$/L with one of the following:
      i) Symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma);
      ii) Have risk factors for bleeding (i.e., on anticoagulant, lifestyle that predisposes member to trauma, comorbidity such as peptic ulcer disease, undergoing medical procedure where blood loss is anticipated); AND
5. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with ONE of the following treatments:
   a) Corticosteroids (prednisone, prednisolone, methylprednisolone, and dexamethasone);
   b) Immunoglobulins;
   c) Splenectomy.
6. **Dosage allowed:** Administer 1mcg/kg subcutaneously once weekly, then adjust the weekly dose by increments of 1 mcg/kg until the patient achieves a platelet count ≥ 50 x 10^9/L. Max dose 10 mcg/kg.

If member meets all the requirements listed above, the medication will be approved for 12 weeks.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement in platelet count from baseline; AND
3. Member's platelet count is less than 400 x 109/L.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource Pharmacy Policy Statement
Marketplace
NPlate

CareSource considers NPlate (romiplostim) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Any cause of thrombocytopenia other than chronic ITP
- Chronic Hepatitis C (CHC) Thrombocytopenia
- ITP with previous documented failure of Nplate
- Severe aplastic anemia
- Thrombocytopenia due to Myelodysplastic syndrome (MDS)

References:

1. Nplate [Package Insert]. Thousand Oaks, CA: Amgen, Inc.; October, 2017.
2. Diagnosis and treatment of idiopathic thrombocytopenic purpura: recommendations of the American Society of Hematology. Ann Intern Med. 1997 Feb 15;126(4):319-26.
3. Cooper N, Terrinoni I, Newland A. The efficacy and safety of romiplostim in adult patients with chronic immune thrombocytopenia. Ther Adv Hematol. 2012 Oct; 3(5): 291–298.
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6. Kuter DJ, et al. Efficacy of romiplostim in patients with chronic immune thrombocytopenic purpura: a double-blind randomised controlled trial. Lancet. 2008 Feb 2;371(9610):395-403.
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8. Neunert C, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011 Apr 21;117(16):4190-207.

Effective date: 11/01/2019
Revised date: 10/04/2018

Update record:
11/12/2019 New Marketplace policy for NPlate created

CareSource Pharmacy Policy Statement
Marketplace
Ocrevus

Drug Name: Ocrevus (ocrelizumab)
Billing Code: J3590 (1 unit = 1 mg)
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: Max 600 mg every 6 months

Ocrevus (ocrelizumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS (PPMS)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Member must have evidence of at least **one** year of disease progression (worsening of neurological function without remission) documented in chart notes; AND
3. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
4. Member must have **two** of the following:
   a) One or more MRI T2-weighted lesion(s) dissemination in space in the brain in periventricular, juxtacortical or infratentorial regions;
   b) Two or more MRI T2-weighted lesions dissemination in space in lesions in the spinal cord;
   c) Evidence in the spinal fluid (and not in serum) of oligoclonal bands or an elevated IgG index; AND
5. Member must have documented negative results on Hepatitis B screening (negative results for both HBsAg and anti-HBV). For patients who are negative for surface antigen (HBsAg) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HBsAg+), consult hepatologist and submit hepatologist's assessment for appropriateness of Ocrevus therapy before starting treatment; AND
6. Member has all necessary immunizations administered (according to immunization guidelines) at least 6 weeks prior to initiation of Ocrevus; AND
7. Member does not have an active infection; AND
8. Ocrevus is not being used in combination with other Multiple Sclerosis therapies (*Note:* When switching from drugs with prolonged immune effects, such as daclizumab, fingolimod, natalizumab, teriflunomide, or mitoxantrone, consider the duration and mode of action of these drugs because of additive immunosuppressive effects when initiating Ocrevus).
9. **Dosage allowed:** 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.

If member meets all the requirements listed above, the medication will be approved 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Doses of Ocrevus are separated by at least 5 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS),

CareSource Pharmacy Policy Statement
Marketplace
Ocrevus

SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

For **initial** authorization:
1) Member must be 18 years of age or older; AND
2) Member must have evidence of at least **one** year of disease progression (worsening of neurological function without remission) documented in chart notes; AND
3) Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
4) Member must have documented negative results on Hepatitis B screening (negative results for both HBsAg and anti-HBV). For patients who are negative for surface antigen (HBsAg) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HBsAg+), consult hepatologist and submit hepatologist's assessment for appropriateness of Ocrevus therapy before starting treatment; AND
5) Member has all necessary immunizations administered (according to immunization guidelines) at least 6 weeks prior to initiation of Ocrevus; AND
6) Member does not have an active infection; AND
7) Ocrevus is not been used in combination with other multiple sclerosis therapies (*Note:* When switching from drugs with prolonged immune effects, such as daclizumab, fingolimod, natalizumab, teriflunomide, or mitoxantrone, consider the duration and mode of action of these drugs because of additive immunosuppressive effects when initiating Ocrevus); AND
8) Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug).
9) **Dosage allowed:** 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1) Member must be in compliance with all other initial criteria; AND
2) Doses of Ocrevus are separated by at least 5 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ocrevus (ocrelizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis

References:

1. Ocrevus [package insert]. San Francisco, CA; Genentech, Inc: March, 2017.
2. Freeman MS, Thompson EJ, Deisenhammer F, et al: Recommended Standard of Cerebrospinal Fluid Analysis in the Diagnosis of Multiple Sclerosis. A Consensus Statement. Arch Neurol. 2005;62(6):865-870.
3. Andersson M, Alvarez-Cermeno J, Bernardi G, et al: Cerebrospinal fluid in the diagnosis of multiple sclerosis: a consensus report. J Neurol Neurosurg Psychiatry 1994;57:897-902.
4. Fortini AS, Sanders EL, Weinshenker BG, Katzmann JA: Cerebrospinal fluid oligoclonal bands in the diagnosis of multiple sclerosis, isoelectric focusing with the IgG immunoblotting compared with high resolution agarose gel electrophoresis and cerebrospinal fluid IgG index. Am J Clin Pathol 2003:120:672-675.

5. Polman, C. H., Reingold, S. C., Banwell, B., Clanet, M., Cohen, J. A., Filippi, M., Fujihara, K., Havrdova, E., Hutchinson, M., Kappos, L., Lublin, F. D., Montalban, X., O'Connor, P., Sandberg-Wollheim, M., Thompson, A. J., Waubant, E., Weinshenker, B. and Wolinsky, J. S. (2011), Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Ann Neurol., 69: 292–302. doi:10.1002/ana.22366.

Effective date: 12/20/2017
Revised date: 12/06/2017

Update record:
11/12/2019 New Marketplace policy for Ocrevus created

CareSource Pharmacy Policy Statement
Marketplace
Onpattro

Drug Name: Onpattro (patisiran)
Billing Code: J3490
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: See **Dosage allowed** below

Onpattro (patisiran) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (hATTR)

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with neurologist; AND
3. Member has diagnosis of hATTR confirmed by ALL of the following:
   a) The demonstration of amyloid deposits via tissue biopsy;
   b) Genetic testing confirming TTR gene mutation;
   c) Documentation of familial amyloid polyneuropathy (FAP) stage 1 (unimpaired ambulation; mostly mild sensory, motor, and autonomic neuropathy in the lower limbs) or stage 2 (assistance with ambulation required; mostly moderate impairment progression to the lower limbs, upper limbs, and trunk). See *Appendix* for details on all stages of FAP for your reference; AND
4. Member does **not** have ANY of the following:
   a) Prior liver transplant;
   b) Known human immunodeficiency virus (HIV) infection;
   c) Hepatitis B virus (HBV) and hepatitis C virus (HCV); AND
5. Member is not receiving Onpattro with Vyndagel, Vyndamax or Tegsedi.
6. **Dosage allowed:** For members weighting less than 100 kg: 0.3 mg/kg every 3 weeks IV. For members weighing 100 kg or more, the recommended dosage is 30 mg every 3 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member continues to have FAP stage 1 or stage 2; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., quality of life and motor function improved, neuropathic pain decreased, serum TTR levels reduced); AND
3. Member is not receiving Onpattro with Vyndagel, Vyndamax or Tegsedi.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Onpattro (patisiran) not medically necessary for the treatment of the diseases that are not listed in this document.

CareSource Pharmacy Policy Statement
Marketplace
Onpattro

References:

1. Onpattro [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; August, 2018.
2. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013;8:31.
3. ClinicalTrials.gov Identifier: NCT01960348. APOLLO: The Study of an Investigational Drug, Patisiran (ALN-TTR02), for the Treatment of Transthyretin (TTR)-Mediated Amyloidosis. Available at: https://clinicaltrials.gov/ct2/show/NCT01960348?term=01960348&rank=1.
4. National Institutes of Health (NIH). Transthyretin amyloidosis. Available at: https://ghr.nlm.nih.gov/condition/transthyretin-amyloidosis.

Effective date: 11/01/2019
Revised date: 08/05/2019

Update record:
11/12/2019 New Marketplace policy for Onpattro created

CareSource Pharmacy Policy Statement
Marketplace
Orencia

Drug Name: Orencia (abatacept)
Billing Code: J0129 (1 unit = 10 mg) – infused product
Benefit Type: Medical
Site of Service Allowed: Outpatient/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Actemra, Enbrel, Cimzia, Kevzara, Olumiant and Xeljanz
Quantity Limit: Infused product 100 units per 28 days; Self-administered product 4 per 28 days

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Orencia (abatacept) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

JUVENILE IDIOPATHIC ARTHRITIS (JIA)

For **initial** authorization:
1. Member must be 2 years of age or older with moderate to severe active JIA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have least 6 months of active disease AND have five or more joints involved; AND
5. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
6. Member must have tried and failed treatment with **both** Enbrel and Actemra. Treatment failure requires at least for 12 weeks of therapy with each drug.
7. **Dosage allowed:** Body weight of patient dose (once weekly subcutaneous): 10 to less than 25 kg – 50 mg; 25 to less than 50 kg – 87.5 mg; 50 kg or more – 125 mg. Weight less than 75 kg receive 10 mg/kg intravenously based on the patient's body weight. Pediatric patients weighing 75 kg or more should be administered Orencia following the adult intravenous dosing regimen, not to exceed a maximum dose of 1000 mg. Intravenous dosing has not been studied in patients younger than 6 years of age.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

CareSource Pharmacy Policy Statement
Marketplace
Orencia

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug; AND
5. Member meets at least **one** of the following scenarios:
   a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
   b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response;
   c) Member has predominately non-axial (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine).
6. **Dosage allowed:** Body weight of patient (intravenous): less than 60 kg – 500 mg; 60 to 100 kg – 750 mg; more than 100 kg 1000 mg. Administer by subcutaneous injection once weekly with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, administer a single intravenous infusion (as per body weight categories above), followed by the first 125 mg subcutaneous injection given within a day of the intravenous infusion. Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:
1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented

contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND

5. Member must have tried and failed treatment with at least **two** of the following: Actemra, Enbrel, Cimzia, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug.
6. **Dosage allowed:** Body weight of patient (intravenous): less than 60 kg – 500 mg; 60 to 100 kg – 750 mg; more than 100 kg 1000 mg. Administer by subcutaneous injection once weekly with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, administer a single intravenous infusion (as per body weight categories above), followed by the first 125 mg subcutaneous injection given within a day of the intravenous infusion. Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Orencia (abatacept) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Ankylosing spondylitis
- Crohn's disease
- Hidradenitis suppurativa
- Plaque psoriasis
- Uveitis (children/adolescents)

References:

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March, 2017.
2. American College of Rheumatology. Guidelines for the management of rheumatoid arthritis: American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Arthritis Rheuma. 1996;39(5):713-723.
3. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications Vol. 65, No. 10, October 2013, pp 2499–2512.
4. Kremer JM, et al. Effects of Abatacept in Patients with Methotrexate-Resistant Active Rheumatoid Arthritis: A Randomized Trial. Ann Intern Med. 2006 Jun 20;144(12):865-76.
5. Mease PJ, et al. Efficacy and safety of abatacept, a T-cell modulator, in a randomised, double-blind, placebocontrolled, phase III study in psoriatic arthritis. Ann Rheum Dis. 2017 Sep;76(9):1550-1558.

Effective date: 11/01/2019

CareSource Pharmacy Policy Statement
Marketplace
Orencia

Revised date: 02/26/2019

Update record:
11/12/2019 New Marketplace policy for Orencia created

CareSource Pharmacy Policy Statement
Marketplace
Orthovisc

Drug Name: Orthovisc (sodium hyaluronate)
Billing Code: J7324
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Durolane, Supartz FX, Gelsyn-3
Quantity Limit: 4 injections (4 units)

OSTEOARTHRITIS OF THE KNEE

For **initial** authorization:
1. Member must be 40 years old or older; AND
2. Member must have a diagnosis of osteoarthritis confirmed by radiological evidence (e.g. Kellgren-Lawrence Scale score of grade 2 or greater); AND
3. Medication must be prescribed by an orthopedic surgeon, interventional pain physicians, rheumatologists, physiatrists (PM&R) and all sports medicine subspecialties; AND
4. Member tried and failed an intra-articular corticosteroid injection(s) in which efficacy was < 4 weeks duration; AND
5. Documentation that member tried and failed ALL of the following:
   a) Weight loss attempts or attempts at lifestyle modifications to promote weight loss (only for members with BMI ≥ 30); AND
   b) Sufficient trial (e.g. 2 to 3 months) of non-pharmacologic therapies (bracing/orthotics, physical/occupational therapy); AND
   c) At least 3 simple analgesic therapies (acetaminophen, NSAIDs, oral or topical salicylates); AND
6. Member is not using medication for hip or shoulder related conditions; AND
7. Member is not allergic to avian proteins, feathers, and egg products; AND
8. Member has tried and failed to respond to treatment with Supartz FX or Durolane or Gelsyn-3 (documented in chart notes and confirmed by claims history).
9. **Dosage allowed:** Inject 30 mg (2 mL) once weekly for 3 to 4 weeks (total of 3 to 4 injections).

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must have documented significant pain relief that was achieved with the initial course of treatment; AND
2. Initial course of treatment has been completed for 6 months or longer; AND
3. Member meets all of the criteria for the initial approval.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Orthovisc (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Refractory interstitial cystitis

CareSource Pharmacy Policy Statement
Marketplace
Orthovisc

- Arthropathy – Disorder of shoulder
- Intravitreal tamponade
- Keratoconjunctivitis sicca
- Subacromial impingement, Syndrome of the shoulder

References:

1. Orthovisc [package insert]. Woburn, MA: Anika Therapeutics. N.d.
2. American Academy of Orthopaedic Surgeons. Treatment of Osteoarthritis of the Knee. Evidence-based guideline 2nd Edition. May 2013. Available at: http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf (December 31, 2015).
3. American College of Rheumatology, Subcommittee on Osteoarthritis Guidelines. Recommendations for the medical management of osteoarthritis of the hip and knee: 2012 update. Arthritis Care & Research 2012; 64(4):465-474. Agency for Healthcare Research and Quality (AHRQ). Three Treatments for Osteoarthritis of the Knee: Evidence Shows Lack of Benefit. Clinician's Guide. March, 2011.
4. Goldberg VM, Buckwater MD. Hyaluronans in the treatment of osteoarthritis of the knee: evidence for disease modifying activity. Osteoarthritis and Cartilage March 2005;13(3):216-224.
5. Majeed M. Relationship between serum hyaluronic acid level and disease activity in early rheumatoid arthritis. Ann Rheum Dis September 2004; 63(9): 1166-8.
6. Tascioglu F, Oner C. Efficacy of intra-articular sodium hyaluronate in the treatment of knee osteoarthritis. Clini Rheumatol. 2003;22:112-117.
7. Lo, G H, et al. JAMA. 2003;290:3115-3121. Intra-articular Hyaluronic Acid in Treatment of Knee Osteoarthritis: A Meta- analysis. Retrieved 3/17/2011 from http://jama.ama-assn.org/cgi/reprint/290/23/3115.
8. Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Viscosupplementation for the treatment of osteoarthritis of the knee. *Cochrane Database Syst Rev.* 2006;(2):CD005321.
9. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. Clin Orthop Relat Res. 2007; 455:113-22.
10. Orthovisc. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 17, 2017.
11. Orthovisc. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed May 17, 2017.
12. McGrath AF, McGrath AM, Jessop ZM, et al. A comparison of intra-articular hyaluronic acid competitors in the treatment of mild to moderate knee osteoarthritis. J Arthritis. 2013; 2(1):108. doi:10.4172/2167-7921.1000108.
13. Leighton R, Åkermark C, Therrien R, et. al. NASHA hyaluronic acid vs methylprednisolone for knee osteoarthritis: a prospective, multi-centre, randomized, non-inferiority trial. Osteoarthritis Cartilage. 2014; 22(1):17-25.

Effective date: 11/01/2019
Revised date: 11/05/2019

Update record:
11/12/2019 New Marketplace policy for Orthovisc created

CareSource Pharmacy Policy Statement
Marketplace
Procrit

Drug Name: Procrit (epoetin alfa)
Billing Code: J0885 (Non-ESRD)
Benefit Type: Medical
Site of Service Allowed: Office, Outpatient
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: Vary per diagnosis

Procrit (epoetin alfa) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANEMIA

For **initial** authorization:
1. Medication must be prescribed by an oncologist, a nephrologist, an immunologist or infectious disease specialist; AND
2. Member has documented diagnosis of anemia due to **one** of the following:
   a) Myelodysplastic syndrome;
   b) Chronic Kidney Disease (GFR below 60 mL/min/1.73 m2);
   c) Concomitant Zidovudine treatment in member with HIV-infection;
   d) The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy; AND
3. Member's individual iron status reveals **both** of the following:
   a) Transferrin saturation is at least 20%;
   b) Ferritin is at least 100 mcg/L; AND
4. Member is on supplemental iron therapy (unless serum ferritin level > 800 mcg/L); AND
5. Member's labs show hemoglobin ≤10 g/dL for adults (≤11 g/dL for children) within the last 14 days for initial therapy, OR ≤10.5 g/dL for adults (≤11.5 g/dL for children) currently receiving therapy.
6. **Dosage allowed:** Members with CKD - 50 to 100 Units/kg 3 times weekly (adults) as initial dose and 50 Units/kg 3 times weekly (pediatric patients). Individualize maintenance dose. Intravenous route recommended for members on hemodialysis. Members on Zidovudine due to HIV-infection -100 Units/kg 3 times weekly. Members with cancer - 40,000 Units weekly or 150 Units/kg 3 times weekly (adults); 600 Units/kg intravenously weekly (pediatric patients ≥5 years).

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member's hemoglobin increased, stayed the same and not decreased further (baseline labs and current labs required); AND
2. Red blood cells transfusions are not required or the number of the transfusions has decreased.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource Pharmacy Policy Statement
Marketplace
Procrit

REDUCTION OF ALLOGENEIC RBC TRANSFUSIONS

For **initial** authorization:
1. Medication must be prescribed by an oncologist, a nephrologist, an immunologist or infectious disease specialist; AND
2. Medication is being used for reduction of allogeneic RBC transfusions in member undergoing elective, non-cardiac, nonvascular high-risk surgery at increased risk of or intolerant to transfusions; AND
3. Member's labs show hemoglobin ≤13 g/dL.
4. **Dosage allowed:** 300 Units/kg per day daily for 15 days or 600 Units/kg weekly.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Medication will not be reauthorized.

CareSource considers Procrit (epoetin alfa) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- In members with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy
- In members with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure
- In members with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion
- In members scheduled for surgery who are willing to donate autologous blood
- In members undergoing cardiac or vascular surgery
- As a substitute for RBC transfusions in patients who require immediate correction of anemia

References:

1. Procrit [package insert]. Thousand Oaks, CA: Amgen; September, 2017.
2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology; Cancer- and Chemotherapy- Induced Anemia. V.2.2018. Available at https://www.nccn.org/professionals/physician_gls/pdf/anemia.pdf. Accessed January 30, 2018.
3. Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2011. (May 11, 2011).
4. Young. D. CMS Anemia Drugs Proposal: Bad for Amgen, Good for Patients, 17 May 2007.
5. New risk management program for erythropoiesis-stimulating agents. Aranesp, Procrit, and Epogen Article; Pharmacist's Letter; April 2010; Vol: 26 Hematology / Oncology.
6. Singh AK, Szczech L, Tang KL, et al. Correction of Anemia with Epoetin Alfa in Chronic Kidney Disease, N Engl j Med. 2006; 355:2085-98.
7. Mueller BU, Jacobsen RN, Jarosinski P, et al. Erythropoietin for zidovudine-associated anemia in children with HIV infection.
8. Pediatr AIDS and HIV Infect: Fetus to Adolesc. 1994;5:169-173.
9. Bohlius J, Wilson J, Seidenfeld J, et al., Recombinant Human Erythropoietins and Cancer Patients: Updated Meta-Analysis of 57 Studies Including 9353 Patients. J Natl Cancer Inst. 2006; 98:708-14.
10. Erythropoiesis-stimulating agents in oncology: a study-level meta-analysis of survival and other safety outcomes.

11. Glaspy J, Crawford J, Vansteenkiste J, Henry D, Rao S, Bowers P, Berlin JA, Tomita D, Bridges K, Ludwig H Br J Cancer. 2010;102(2):301. American Society of Clinical Oncology/American Society of Hematology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer.
12. Rizzo JD, Brouwers M, Hurley P, Seidenfeld J, Arcasoy MO, Spivak JL, Bennett CL, Bohlius J, Evanchuk D, Goode MJ, Jakubowski AA, Regan DH, Somerfield MR, American Society of Clinical Oncology, American Society of Hematology; J Clin Oncol. 2010;28(33):4996. National Comprehensive Cancer Network (NCCN) guidelines www.nccn.org. Accessed September 3, 2015.
13. Aliment Pharmacol Ther. 2010 May;31(9):929-37. Epub 2010 Feb 18.Review article: optimizing SVR and management of the haematological side effects of peginterferon/ribavirin antiviral therapy for HCV - the role of epoetin, G-CSF and novel agents.
14. Definition and management of anemia in patients infected with hepatitis C virus. McHutchison JG, Manns MP, Longo DL Liver Int. 2006;26(4):389 MCG 20th edition, 2016.

Effective date: 11/01/2019
Revised date: 10/04/2018

Update record:
11/12/2019 New Marketplace policy for Procrit created

CareSource Pharmacy Policy Statement
Marketplace
Prolia

Drug Name: Prolia (denosumab)
Billing Code: J0897
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include alendronate, ibandronate and zoledronic acid
Quantity Limit: 60 mg every 6 months

Prolia (denosuab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OSTEOPOROSIS

For **initial** authorization:

1. Medication is intended to be used for one the following (see *Appendix* for details on risk factors for fracture for all indications):
   a) Treatment of postmenopausal women with osteoporosis at high risk for fracture;
   b) Treatment to increase bone mass in men with osteoporosis at high risk for fracture;
   c) Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture (member has been taking ≥ 5 mg of prednisone (or equivalent) daily for ≥ 3 months); AND
2. Member's osteoporosis evidenced by one of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, total, and/or 33% (one-third) radius;
   b) Low-trauma spine or hip fracture (regardless of BMD);
   c) Osteopenia or low bone mass (T-score between –1 and –2.5) with a fragility fracture of proximal humerus, pelvis, or possibly distal forearm;
   d) Osteopenia or low bone mass and high FRAX® fracture probability (a 10-year probability for major osteoporotic fracture is ≥ 20% or the 10-year probability of hip fracture is ≥ 3%); AND
3. Member does **not** have ANY of the following:
   a) Uncorrected hypocalcemia;
   b) Dental disease;
   c) History of receiving Xgeva within the past 6 months; AND
4. Member was instructed to take calcium 1,000 mg daily and at least 400 IU of vitamin D daily; AND
5. Member cannot take oral bisphosphonate therapies (i.e., alendronate and/or ibandronate) as evidenced by one or more of the following:
   a) Esophogeal dysmotility or varices;
   b) Member is unable to stand or sit upright for 30-60 minutes;
   c) Presence of anatomic or functional esophageal abnormalities that might delay tablet transit (e.g., achalasia, stricture, or dysmotility);
   d) Presence of documented or potential GI malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.);
   e) Member has experienced intolerance to or treatment failure of one or more bisphosphonate medications;
   f) Member has a history of non-adherence to oral bisphosphonate medications; AND
6. Member has had a documented trial and inadequate response to zoledronic acid.

7. **Dosage allowed:** 60 mg every 6 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member meets all initial criteria; AND
2. Chart notes have been provided that show the member has shown an increase in bone mineral density.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

BONE LOSS (for nonmetastatic prostate cancer or for breast cancer)

For **initial** authorization:
1. Medication is intended to be used for one the following (see *Appendix* for details on risk factors for fracture for all indications):
   a) Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (e.g., goserelin, leuprolide, bicalutamide) for nonmetastatic prostate cancer;
   b) Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, letrozole) for breast cancer;
2. Member has a bone mineral density (BMD) T-score at the lumbar spine, total hip, or femoral neck –1 or less; AND
3. Member does **not** have ANY of the following:
   a) Uncorrected hypocalcemia;
   b) Dental disease;
   c) History of receiving Xgeva within the past 6 months; AND
4. Member was instructed to take calcium 1,000 mg daily and at least 400 IU of vitamin D daily; AND
5. Member cannot take oral bisphosphonate therapies (i.e., alendronate and/or ibandronate) as evidenced by one or more of the following:
   a) Esophogeal dysmotility or varices;
   b) Member is unable to stand or sit upright for 30-60 minutes;
   c) Presence of anatomic or functional esophageal abnormalities that might delay tablet transit (e.g., achalasia, stricture, or dysmotility);
   d) Presence of documented or potential GI malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.);
   e) Member has experienced intolerance to or treatment failure of one or more bisphosphonate medications;
   f) Member has a history of non-adherence to oral bisphosphonate medications.
6. **Dosage allowed:** 60 mg every 6 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member meets all initial criteria; AND
2. Chart notes have been provided that show the member has shown an increase in bone mineral density.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource Pharmacy Policy Statement
Marketplace
Prolia

CareSource considers Prolia (denosumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Bone metastases from solid tumors
- Giant Cell Tumor of Bone
- Multiple Myeloma
- Paget's disease

References:

1. Prolia (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; June 2018.
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Effective date: 11/01/2019
Revised date: 07/19/2019

Update record:
11/12/2019 New Marketplace policy for Prolia created

CareSource Pharmacy Policy Statement
Marketplace
Radicava

Drug Name: Radicava (edaravone injection)
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: N/A

Radicava (edaravone injection) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

AMYOTROPHIC LATERAL SCLEROSIS (ALS)

For **initial** authorization:
1. Provider submitted detailed chart notes confirming member's Definite or Probable ALS based on El Escorial revised criteria; AND
2. Member can eat a meal, excrete, or move with oneself alone, and perform most functions of everyday life with little to no assistance (chart notes required); AND
3. Member does not have Parkinson's disease, schizophrenia, dementia, renal failure, or hypersensitivity to Radicava (edaravone); AND
4. Member's functionality retained most activities of daily living and defined as a total of 20 points or better on the ALS Functional Rating Scale – Revised (ALSFRS-R), and submitted with chart notes (i.e. scores for speech, salivation, swallowing, handwriting, walking, etc.).
5. **Dosage allowed:** 60 mg administered as an intravenous infusion over 60 minutes as follows: Initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period; Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Radicava (edaravone injection) not medically necessary for the treatment of the diseases that are not listed in this document.

References:

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Effective date: 11/01/2019
Revised date: 09/15/2017

Update record:
11/12/2019 New Marketplace policy for Radicava created

CareSource Pharmacy Policy Statement
Marketplace
Remicade

Drug Name: Remicade (infliximab)
Billing Code: J1745 (1 unit = 10 mg or 1 x 100 mg vial = 10 units)
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Actemra, Cimzia, Cosentyx, Enbrel, Kevzara, Olumiant, Otezla, Siliq and Xeljanz
Quantity Limit: 1200 mg (120 units per dose)

Remicade (infliximab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANKYLOSING SPONDYLITIS (AS)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member has had back pain for 3 months or more that began before the age of 50; AND
5. Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
6. Member shows at least **one** of the following signs or symptoms of Spondyloarthritis:
   a) Arthritis;
   b) Elevated serum C-reactive protein;
   c) Inflammation at the tendon, ligament or joint capsule insertions;
   d) Positive HLA-B27 test;
   e) Limited chest expansion;
   f) Morning stiffness for 1 hour or more; AND
7. Member meets at least **one** of the following scenarios:
   a) Member has Axial (spinal) disease;
   b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response;
   c) Member has tried and failed to respond to treatment with at least **two** prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
8. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia and Cosentyx. Treatment failure requires at least for 12 weeks of therapy with each drug.
9. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

If member meets all the requirements listed above, the medication will be approved for 12 months.

CareSource Pharmacy Policy Statement
Marketplace
Remicade

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CROHN'S DISEASE (CD)

For **initial** authorization:
1) Member is 6-17 years of age with moderately to severely active CD as defined by Pediatric Crohn's Disease Activity Index (PCDAI) greater than 30 OR member is 18 years of age or older with moderately to severely active non-fistulizing CD as defined by Crohn's Disease Activity Index (CDAI) greater than 220 and less than 400; AND
2) Member has had a trial and inadequate response to at least **one** of the following:
   a) 6-mercaptopurine;
   b) Azathioprine;
   c) Methotrexate;
   d) Corticosteroid(s); OR
3) Member is 18 years of age or older with fistulizing CD; AND
4) Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
5) Medication must be prescribed by a gastroenterologist.
6) **Dosage allowed:** 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter. If no response by week 14, consider discontinuing therapy.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
4. Documented member's PCDAI or CDAI score improvement.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a dermatologist or rheumatologist; AND
4. Member has PsO for 6 months or longer; AND

5. Member is not going to receive systemic therapy or phototherapy while on Remicade; AND
6. Member's plaque psoriasis involving 10% or more of the body surface area (BSA) or 5% or more of BSA if psoriasis involves sensitive areas (hands, feet, face, or genitals); AND
7. Member's Psoriasis Area and Severity Index (PASI) greater than or equal to 12; AND
8. Member has tried and failed to respond to treatment with at least **one** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments (tanning beds emit mostly UVA light and therefore would not meet this criteria)).
   c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
9. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least a 12 week trial; AND
10. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq. Treatment failure requires at least for 12 weeks of therapy with each drug.
11. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's PASI score improvement, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member meets at least **one** of the following scenarios:
   a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
   b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) and has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response;
   c) Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID

taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine); AND

5. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug.
6. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Medication must be used in combination with methotrexate, or if intolerant to methotrexate, another immunosuppressant (i.e., azathioprine, hydroxychloroquine, cyclosporine, etc.); AND
5. Member must have tried and failed treatment with at least **two** non-biologic DMARDS OR must have a contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks (non-biologic DMARDs include: methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide); AND
6. Member has tried and failed treatment with at least **two** of the following: Actemra, Cimzia, Enbrel, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug.
7. **Dosage allowed:** 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource Pharmacy Policy Statement
Marketplace
Remicade

ULCERATIVE COLITIS (UC)

For **initial** authorization:
1. Member is 6-17 years of age with moderate to severe active UC as defined by Pediatric Ulcerative Colitis Activity Index (PUCAI) of 35 or greater OR member is 18 years of age or older with moderately to severely active UC as defined by Mayo score of 6 or greater with an endoscopy subscore of 2 or 3; AND
2. Medication must be prescribed by a gastroenterologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member must have tried and failed treatment with at least with **one** or more of the following:
   a) 6-mercaptopurine;
   b) Azathioprine;
   c) Methotrexate;
   d) Oral corticosteroids;
   e) Salicylates.
5. **Dosage allowed:** 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Remicade (infliximab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Amyloid angiopathy
- Asthma
- Behcet's disease
- Birdshot retinochoroidopathy
- Bronchiolitis obliterans
- Central nervous system amyloidosis
- Chemotherapy induced enterocolitis (not due to Yervoy or Opdivo)
- Chronic immune-mediated myelitis
- Chronic obstructive pulmonary disease
- Cogan's syndrome
- Corneal ulcer
- Cranial nerve palsy
- Cystoid macular degeneration

CareSource Pharmacy Policy Statement
Marketplace
Remicade

- Disc herniation-induced sciatica
- Discoid lupus erythematosus
- Eczema
- Eosinophilic fasciitis
- Graft-versus-host-disease
- Granuloma annulare
- Granulomatous angiitis
- Granulomatous mastitis
- Hepatitis C genotype 1
- IgG4-related disease
- Infectious uveitis
- Iritis
- Juvenile idiopathic arthritis
- Kawasaki syndrome
- Localized scleroderma/morphea
- Membranous glomerulopathy
- Microscopic colitis
- Multifocal osteomyelitis (e.g., (chronic recurrent multifocal osteomyelitis (CRMO))
- Neurosarcoidosis
- Nodular scleritis
- Panniculitis
- Polyarteritis nodosa
- Polymyositis
- Prevention of post-operative recurrence of Crohn's disease
- Rejection following small bowel transplantation
- Relapsing polychondritis
- Scleroderma
- Sjogren's syndrome
- Still's disease
- Systemic lupus erythematosus
- Takayasu arteritis
- Tolosa-Hunt syndrome
- Tubulo-interstitial nephritis with uveitis (TINU) syndrome
- Wegener's granulomatosis/Wegener's peripheral neuropathy.

References:

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6. Sandborn, W., Binion, D., Persley, K., Atreja, A., & Kosinski, L. (2014). AGA Institute Guidelines for the Identification, Assessment and Initial Medical Treatment in Crohn's Disease: Clinical Decision Support Tool. AGA Institute. Retrieved August 14, 2015, from www.gastro.org/IBDcarepathway.
7. Foundation for Sarcoidosis Research.http://www.stopsarcoidosis.org/wp-content/uploads/2013/03/FSR-Physicians-Protocol1.pdf.
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11. American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Guidelines for the management of rheumatoid arthritis: Arthritis Rheum. 1996;39(5):713-723.
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Effective date: 11/01/2019
Revised date: 02/26/2019

Update record:
11/12/2019 New Marketplace policy for Remicade created

CareSource Pharmacy Policy Statement
Marketplace
Ruconest

Drug Name: Ruconest (C1 esterase inhibitor (rabbit-derived))
Billing Code: J0596
Benefit Type: Medical
Site of Service Allowed: Home/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Berinert and Firazyr
Quantity Limit: 4 vials per fill (8 vials per 30 days)

Ruconest (C1 esterase inhibitor (rabbit-derived)) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:

1. Member must be 13 years of age or older, and medication is being used **for the treatment of acute HAE attacks** (excluding laryngeal HAE attacks and acquired angioedema); AND
2. Medication must be prescribed by or in consultation with a provider specializing in allergy, immunology, or hematology; AND
3. Member has documented trial and failure of or contraindication to **both** Firazyr and Berinert (Chart notes required); AND
4. Member must have a confirmed diagnosis of HAE as **one** of the following:
   a) Type 1 HAE documented in chart notes with ALL of the following (*Note:* tests listed below must be repeated for confirmation of diagnosis):
      i) Low levels (below the limits of the laboratory's normal reference range) of C4, C1-INH antigenic protein and C1-INH functional level; AND
      ii) Positive family history of angioedema OR earlier age of onset (before age 30) with normal C1q antigenic protein level;
   b) Type 2 HAE documented in chart notes with ALL of the following (*Note:* tests listed below must be repeated for confirmation of diagnosis):
      i) Normal or elevated level of C1-INH antigenic protein (as defined by performing lab); AND
      ii) Low level (below the limits of the laboratory's normal reference range) C4 and C1-INH functional; AND
5. Medication is **not** being used in combination with Berinert, Firazyr, or Kalbitor; AND
6. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.
7. **Dosage allowed:** weight based dosing per package insert; do not exceed 4200 IU per dose and no more than 2 doses within 24 hours.

Note: *Personal documentation (log book, journal, etc.) of medication use will be necessary for reauthorization. Prescribers should be aware and make their patients aware of this requirement for reauthorization.*

If member meets all the requirements listed above, the medication will be approved for 3 months.

CareSource Pharmacy Policy Statement
Marketplace
Ruconest

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
3. Log of medication use supported by medical chart or by claims data has been provided.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Ruconest (C1 esterase inhibitor (rabbit-derived)) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acquired angioedema (AAE)
- HAE prophylactic therapy
- Treatment of laryngeal HAE attacks

References:

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Effective date: 11/01/2019
Revised date: 08/28/2017

Update record:
11/12/2019 New Marketplace policy for Ruconext created

CareSource Pharmacy Policy Statement
Marketplace
Simponi Aria

Drug Name: Simponi Aria (golimumab)
Billing Code: J1602 (1 unit = 1 mg)
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Actemra, Enbrel, Cimzia, Cosentyx, Kevzara, Olumiant, Otezla and Xeljanz
Quantity Limit: 120 units every 56 days

Simponi Aria (golimumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANKYLOSING SPONDYLITIS (AS)

For **initial** authorization:
1) Member must be 18 years of age or older; AND
2) Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3) Medication must be prescribed by a rheumatologist; AND
4) Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia and Cosentyx. Treatment failure requires at least for 12 weeks of therapy with each drug; AND
5) Member has had back pain for 3 months or more that began before the age of 50; AND
6) Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
7) Member shows at least **one** of the following signs or symptoms of Spondyloarthritis:
   a) Arthritis;
   b) Elevated serum C-reactive protein;
   c) Inflammation at the tendon, ligament or joint capsule insertions;
   d) Positive HLA-B27 test;
   e) Limited chest expansion;
   f) Morning stiffness for 1 hour or more; AND
8) Member meets at least **one** of the following scenarios:
   a) Member has Axial (spinal) disease;
   b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
9) Member has tried and failed to respond to treatment with at least **two** prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response.
10) **Dosage allowed:** 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND

3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:
1) Member must be 18 years of age or older; AND
2) Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3) Medication must be prescribed by a rheumatologist or dermatologist; AND
4) Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug; AND
5) Member meets at least **one** of the following scenarios:
   a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
   b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response;
   c) Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine).
6) **Dosage allowed:** 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:
1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND

4. Medication is being given in combination with methotrexate or with another immunosuppressive agent if the member cannot tolerate methotrexate; AND
5. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
6. Member has tried and failed treatment with at least **two** of the following: Actemra, Cimzia, Enbrel, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug.
7. **Dosage allowed:** 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Simponi Aria (golimumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Asthma
- Cellulitis
- Crohn's disease
- Dissecting scalp cellulitis
- For use in combination with TNF-inhibitors (Enbrel, Humira, Remicade, Kineret)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis
- Takayasu's arteritis
- Ulcerative colitis
- Vogt-Koyanagi

CareSource Pharmacy Policy Statement
Marketplace
Simponi Aria

References:

1. Simponi Aria [prescribing information]. Horsham, PA; Janssen Biotech, Inc.: October, 2017.
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5. Higgins J, Green S, editors. Cochrane handbook for systematic reviews of interventions, Version 5.1.0 [updated March 2011]. The Cochrane Collaboration. Available from: URL:www.cochrane-handbook.org.
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7. Smolen JS. Insights into the efficacy of golimumab plus methotrexate in patients with active rheumatoid arthritis who discontinued prior anti-tumour necrosis factor therapy: post-hoc analyses from the GO-AFTER study. Ann Rheum Dis. 2014 Oct;73(10):1811-8.
8. Li Z, et al. Efficacy and safety results from a Phase 3, randomized, placebo-controlled trial of subcutaneous golimumab in Chinese patients with active rheumatoid arthritis despite methotrexate therapy. Int J Rheum Dis. 2016 Nov;19(11):1143-1156.
9. Inman RD, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: results of a randomized, double-blind, placebo-controlled, phase III trial. Arthritis Rheum. 2008 Nov;58(11):3402-12.
10. Sieper J, et al. A randomized, double-blind, placebo-controlled, sixteen-week study of subcutaneous golimumab in patients with active nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2015 Oct;67(10):2702-12.
11. Kavanaugh A, et al. Golimumab in psoriatic arthritis: one-year clinical efficacy, radiographic, and safety results from a phase III, randomized, placebo-controlled trial. Arthritis Rheum. 2012 Aug;64(8):2504-17.
12. Michelon MA, et al. Role of golimumab, a TNF-alpha inhibitor, in the treatment of the psoriatic arthritis. Clin Cosmet Investig Dermatol. 2010;3:79-84.

Effective date: 11/01/2019
Revised date: 02/26/2019

Update record:
11/12/2019 New Marketplace policy for Simponi Aria created

CareSource Pharmacy Policy Statement
Marketplace
Soliris

Drug Name: Soliris (eculizumab)
Billing Code: J1300
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: 1,800 mg for a 28 day supply

Soliris (eculizumab) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS)

For **initial** authorization:
1. Member has diagnosis of aHUS supported by the absence of Shiga toxin-producing E. coli infection and with ADAMTS13 activity level >5% documented in chart notes; AND
2. Member has ALL of the following documented in chart notes:
   a) Platelet count ≤150 x 10^9/L;
   b) Evidence of hemolysis (e.g., an elevation in serum Lactic Acid Dehydrogenase (LDH));
   c) Serum creatinine above the upper limits of normal, without the need for chronic dialysis; AND
3. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); AND
4. Member does **not** have ANY of the following:
   a) History of malignancy within 5 years;
   b) HIV;
   c) Infection-related or identified drug exposure-related hemolytic-uremic syndrome (HUS);
   d) HUS related to bone marrow transplant (BMT) or to vitamin B12 deficiency;
   e) Systemic Lupus Erythematosus (SLE) or antiphospholipid antibody positivity or syndrome;
   f) Member is on chronic intravenous immunoglobulin (IVIG) within 8 weeks or chronic Rituximab therapy within 12 weeks.
5. **Dosage allowed:** 3,600 mg/28 days for initial fill, then 2,400 mg/28 days for subsequent fills.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has an increase in mean platelet counts from baseline and signs of complement-mediated thrombotic microangiopathy (TMA) activity were reduced with Soliris (eculizumab) therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

GENERALIZED MYASTHENIA GRAVIS (gMG)

For **initial** authorization:

CareSource Pharmacy Policy Statement
Marketplace
Soliris

1. Member is 18 years of age or older with diagnosis of gMG as confirmed by ALL of the following criteria documented in chart notes:
   a) Positive serologic test for anti-AChR antibodies;
   b) MG-Activities of Daily Living (MG-ADL) total score ≥ 6;
   c) Failed treatment with any **one** of the following:
      i) At least 2 immunosuppressive therapies (e.g. corticosteroid, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) over 1 year or more; OR
      ii) At least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); AND
2. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); AND
3. Member does **not** have a history of thymectomy (within the past 2 months) or thymus cancer; AND
4. Member did **not** use:
   a) Rituximab within 6 months prior to therapy; OR
   b) IVIG or PE within 4 weeks prior to therapy.
5. **Dosage allowed:** 900 mg weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement in MG-ADL score while on Soliris (eculizumab) therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

For **initial** authorization:
1. Member with diagnosis of PNH as confirmed by flow cytometry (PNH type III red cells or GPI-AP-deficient polymorphonuclear cells (PMNs)); AND
2. Medication is prescribed by a hematologist or nephrologist; AND
3. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); AND
4. Member has LDH levels >1.5 times the upper limit of normal documented in chart notes; AND
5. Member has **one** or more of the following documented in chart notes:
   a) History of at least 1 blood transfusion within the past 24 months due to anemia or anemia related symptoms or personal beliefs precluding transfusion;
   b) Presence of organ damage due to chronic hemolysis.
6. **Dosage allowed:** 2,400 mg/28 days for initial fill then 1,800 mg/28 days for subsequent fills.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Soliris (eculizumab) therapy.

CareSource Pharmacy Policy Statement
Marketplace
Soliris

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Soliris (eculizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

References:

1. Soliris (eculizumab) [prescribing information]. New Haven, CT: Alexion Pharmaceuticals Inc; January 2017.
2. Eculizumab. In: Lexi-Drugs Online, Hudson, OH: Lexi-Comp, Inc. 2009; [July 17, 2017. Accessed July 17, 2017.] http://online.lexi.com.
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8. Kaplan BS, Ruebner RL, Spinale JM, Copelovitch L. Current treatment of atypical hemolytic uremic syndrome. *Intractable Rare Dis Res.* 2014;3(2):34-35. Doi: 10.5582/irdr.2014.01001.
9. Cheong H, Jo SK, Yoon SS, et. al. Clinical practice guidelines for the management of atypical hemolytic uremic syndrome in Korea. *J Korean Med Sci*. 2016;31:1516-1528. Doi: 10.3346/jkms.2016.31.10.1516.
10. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016 Jul 26;87(4):419-25. doi: 10.1212/WNL.0000000000002790.
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12. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT00844545. Open Label Controlled Trial of Eculizumab in Adult Patients With Plasma Therapy-Resistant aHUS (aHUS). July 23, 2015. Available at: https://clinicaltrials.gov/ct2/show/NCT00844545?term=eculizumab&recrs=adef&cond=ATYPICAL+HEMOLYTIC+UREMIC+SYNDROME+%28aHUS%29&rank=6.
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14. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT01997229. Safety and Efficacy of Eculizumab in Refractory Generalized Myasthenia Gravis (REGAIN Study). March 3, 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT01997229?term=eculizumab&recrs=adef&cond=GENERALIZED+MYASTHENIA+GRAVIS&rank=1.
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CareSource Pharmacy Policy Statement
Marketplace
Soliris

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Effective date: 11/01/2019
Revised date: 11/14/2017

Update record:
11/12/2019 New Marketplace policy for Soliris created

CareSource Pharmacy Policy Statement
Marketplace
Spinriza

Drug Name: Spinraza (nusinersen)
Billing Code: J2326 (1 unit = 0.1 mg)
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: 12 mg or 5 mL per administration

Spinraza (nusinersen) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

SPINAL MUSCULAR ATROPHY (SMA)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a neurologist with expertise in the treatment of SMA; AND
2. Member has documented diagnosis of SMA type I, II or III confirmed by BOTH of the following diagnostic test results (both a and b):
   a) The mutation or deletion of genes in chromosome 5q resulting in **one** of the following:
      i) homozygous gene deletion OR mutation (e.g., homozygous deletion of exon 7 at locus 5q13);
      ii) compound heterozygous mutation (e.g., deletion of SMN1 exon 7(allele 1) and mutation of SMN1 (allele 2));
   b) Genetic testing confirming 2 or 3 copies of SMN2; AND
3. Member has documented laboratory tests at baseline and prior to each dose of Spinraza as listed below:
   a) Platelet count; AND
   b) Prothrombin time; activated partial thromboplastin time; AND
   c) Quantitative spot urine protein testing; AND
4. Member has documentation of baseline of at least **one** of the following exams (based on patient age and motor ability):
   a) Hammersmith Infant Neurological Exam (HINE) (infant to early childhood);
   b) Hammersmith Functional Motor Scale Expanded (HFMSE);
   c) Upper Limb Module (ULM) Test (Non ambulatory);
   d) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND); AND
5. Member's gestational age is 37 to 42 weeks for singleton births or 34 to 42 weeks for twins; AND
6. Member's documented oxygen saturation is ≥ 92% (awake or asleep) without any supplemental oxygen or respiratory support; AND
7. Member does not have shunt or central nervous system (CNS) catheter; AND
8. Member has no history of bacterial meningitis or viral encephalitis; AND
9. Medication must not be concomitantly used with Zolgensma (discontinuation of Spinraza prior to Zolgensma therapy is required and Spinraza will not be reauthorized after Zolgensma infusion).
10. **Dosage allowed:** Initiate Spinraza treatment with 4 loading doses (12 mg (5 mL) per administration). The first three loading doses should be administered at 14-day intervals, the 4th loading dose should be administered 30 days after the 3rd dose. A maintenance dose should be administered once every 4 months thereafter.

If member meets all the requirements listed above, the medication will be approved 6 months.

CareSource Pharmacy Policy Statement
Marketplace
Spinriza

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member has documentation of positive clinical improvement from pretreatment baseline status in spinal muscular atrophy-associated symptoms or maintenance (not worsening) of the disease state (e.g., decreased decline in motor function, increased ability to kick, increased in the motor milestones of head control, rolling, sitting, crawling, standing, or walking, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Spinraza (nusinersen) not medically necessary for the treatment of the diseases that are not listed in this document.

References:

1. Spinraza [package insert]. Cambridge, MA; Biogen Inc.; December, 2016.
2. Markowitz JA, Singh P, Darras BT. Spinal Muscular Atrophy: A Clinical and Research Update. Pediatric Neurology 46 (2012) 1-12.
3. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Infants With Spinal Muscular Atrophy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Available from: https://clinicaltrials.gov/show/NCT02193074. NLM Identifier: NCT02193074.
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Effective date: 11/01/2019
Revised date: 06/11/2019

Update record:
11/12/2019 New Marketplace policy for Spinraza created

CareSource Pharmacy Policy Statement
Marketplace
Spravato

Drug Name: Spravato (esketamine)
Billing Code: J3490
Benefit Type: Medical
Site of Service Allowed: Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: See **Dosage allowed** below

Spravato (esketamine) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

TREATMENT RESISTANT DEPRESSION

For **initial** authorization:
1. Member has diagnosis of treatment resistant depression; AND
2. Member is 18 years old or older; AND
3. Medication must be used in conjunction with an oral antidepressant (e.g., citalopram, escitalopram, fluoxetine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, nortriptyline, bupropion, trazodone); AND
4. Member has had a 60-day trial and failure of **at least two** of the following:
   a) Selective Serotonin Reuptake Inhibitor;
   b) Selective Norepinephrine Reuptake Inhibitor;
   c) Tricyclic Antidepressant;
   d) Monoamine Oxidase Inhibitor;
   e) Bupropion;
   f) Mirtazapine;
   g) Trazodone; AND
5. Documentation of the member's baseline depression status using an appropriate rating scale (e.g., PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D).
6. **Dosage allowed:** Weeks 1-4: Maximum of 8 kits per month for 56 mg device and 7 kits per month for 84 mg device; Weeks 5-8: Maximum of 4 kits per month.

If member meets all the requirements listed above, the medication will be approved for 2 months.

For **reauthorization**:
1. Documented maintenance of clinical improvement in depression symptoms as measured by improvement from baseline score on an appropriate rating scale.
2. **Dosage allowed:** Dose: 4 kits per 28 days.

Note: Healthcare site, dispensing pharmacy, and patient must all be enrolled in the Spravato REMS program.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 1 year.

CareSource Pharmacy Policy Statement
Marketplace
Spravato

CareSource considers Spravato (esketamine) not medically necessary for the treatment of the diseases that are not listed in this document.

References:

1. Spravato [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May, 2019.
2. A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Flexible Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression (TRANSFORM-2). Janssen Research & Development. NCT0241858. April 2019. Available at: https://clinicaltrials.gov/ct2/show/NCT02418585?term=02418585&rank=1.
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Effective date: 11/01/2019
Revised date: 05/31/2019

Update record:
11/12/2019 New Marketplace policy for Spravato created

CareSource Pharmacy Policy Statement
Marketplace
Synagis

Drug Name: Synagis (palivizumab)
Billing Code: 90378 (1 unit = 50 mg)
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: 200 mg per month

Synagis (palivizumab) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PREVENTION OF RESPIRATORY TRACT DISEASE CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV)

For **initial** authorization:

1. Request must be made during the RSV season (*November 1st through March 31st*) AND initiation of injections should be timed with the onset of laboratory confirmed cases of RSV activity in the community, no earlier than November 1, 2019; AND
2. Member is < 12 months old at the beginning of the RSV season AND meet **one** of the following criteria (chart notes must be provided to support evidence):
   a) Member was born < 29 weeks, 0 days' gestation;
   b) Member has Chronic Lung Disease (CLD) of prematurity (defined as gestational age < 32 weeks, 0 days and a requirement for > 21% oxygen for at least the first 28 days after birth);
   c) Member has hemodynamically significant Congenital Heart Disease (CHD) with **one** or more of the following:
      ~~i)~~ Acyanotic heart disease (e.g., atrial septal defect (ASD), ventricular septal defect (VSD), patent ductus arteriosus (PDA), etc.), AND member is receiving medication to control congestive heart failure (CHF) AND will require cardiac surgical procedures;
      ii) Moderate to severe pulmonary hypertension;
      iii) Cyanotic heart defect (e.g., coarctation or complete interruption of the aorta, Ebstein anomaly, hypoplastic left heart syndrome, Tetralogy of Fallot (TOF), total anomalous pulmonary venous connection (TAPVC), transposition of the great arteries (TGA), truncus arteriosus, tricuspid atresia, etc.);
      iv) Previous cardiac or cardiopulmonary surgical procedures (e.g., cardiac bypass, at the conclusion of extracorporeal membrane oxygenation (ECMO), etc.);
   d) Member has pulmonary abnormalities or neuromuscular disorder that impairs the ability to clear secretions from the upper airways;
   e) Member is profoundly immunocompromised during the RSV season (e.g., concurrent chemotherapy, stem cell transplantation, organ transplantation, etc.);
   f) Member undergoes cardiac transplantation during the RSV season;
   g) Member has Cystic Fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life; OR
3. Member is 12 – 24 months old at the beginning of the RSV season AND meet **one** of the following criteria (chart notes must be provided to support evidence):

a) Member was born < 32 weeks, 0 days' gestation **and** has CLD of prematurity that required at least 28 days of oxygen after birth and who continues to require supplemental oxygen, chronic systemic corticosteroid therapy, diuretics, or bronchodilator therapy during 6 months before the the start of the second RSV season;
b) Member is profoundly immunocompromised during the RSV season (e.g., concurrent chemotherapy, stem cell transplantation, organ transplantation, etc.);
c) Member undergoes cardiac transplantation during the RSV season;
d) Member has Cystic Fibrosis with **one** of the following:
   i) Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, or abnormalities on chest radiography or chest computed tomography that persist when stable);
   ii) Weight for length less than the 10th percentile on a pediatric growth chart.

4. **Dosage allowed:** Administer 15 mg/kg intramuscularly prior to beginning of RSV season and continue every month for a total of 5 doses or until the end of the RSV season.

If member meets all the requirements listed above, the medication will be approved for 5 months or until the end of the RSV season (March 31, 2020), whichever comes first.

CareSource considers Synagis (palivizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Prophylaxis of Health Care-Associated RSV Disease
- RSV prophylaxis for children with Down syndrome
- RSV prophylaxis for children who were previously infected with RSV in the current season
- RSV prophylaxis for infants and children with mild cardiomyopathy
- RSV prophylaxis for infants and children with hemodynamically insignificant heart disease (e.g. Secundum atrial septal defect, small ventricular septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coartation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children with CHD in the second year of life
- Treatment of RSV Disease

References:

1. Palivizumab (Synagis) [prescribing information]. Gathersburg, MD: MedImmune, LLC; May 2017.
2. Brady MT, Byington CL, Davies HD, et al. Updated guidance for palivizumab among infants and young children at increased risk of hospitalization for RSV infection. *Pediatrics*. 2014 Aug;134(2):415-20. doi: 10.1542/peds.2014-1665.
3. Feltes T, Cabalka A, Meissner H, et al. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. *J Pediatr.* 2003 Oct;143(4):532-40.
4. Weinrauch LA. Cyanotic heart disease: MedlinePlus. Verimed Healthcare Network: October 2015. https://medlineplus.gov/ency/article/001104.htm.

5. Anderson EJ, Krilov LR, DeVincenzo JP, et al. SENTINEL1: An Observational Study of Respiratory Syncytial Virus Hospitalizations among U.S. Infants Born at 29 to 35 Weeks' Gestational Age Not Receiving Immunoprophylaxis. Thieme Medical Publishers, Inc. May 27, 2016.
6. Kong AM, Krilov LR, Fergie J, et al. The 2014–2015 National Impact of the 2014 American Academy of Pediatrics Guidance for Respiratory Syncytial Virus Immunoprophylaxis on Preterm Infants Born in the United States. Thieme Medical Publishers, Inc. July 26, 2017.
7. Goldstain M, Krilov LR, Fergie J, et al. Respiratory Syncytial Virus Hospitalizations among U.S. Preterm Infants Compared with Term Infants Before and After the 2014 American Academy of Pediatrics Guidance on Immunoprophylaxis: 2012–2016. Thieme Medical Publishers, Inc. April 26, 2018.
8. MARP ID SENTINEL1 ID Week 2016 poster ML-3016-US-0098.
9. 2018 PAS Poster Goldstein et al. RSVHs Before and Two Seasons After 2014 AAP Guidance on RSVIP.
10. Rajah B, Sanchez PJ, Garcia-Maurino C, et al. Impact of the Updated Guidance for Palivizumab Prophylaxis against Respiratory Syncytial Virus Infection: A Single Center Experience. *J Pediatr* 2016. November 15, 2016.

Effective date: 11/01/2019
Revised date: 09/04/2019

Update record:
11/12/2019 New Marketplace policy for Synagis created

CareSource Pharmacy Policy Statement
Marketplace
Synvisc-One

Drug Name: Synvisc-One (sodium hyaluronate)
Billing Code: J7325
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Durolane, Supartz FX, Gelsyn-3
Quantity Limit: 1 injection (48 unit)

Synvisc-One (sodium hyaluronate) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OSTEOARTHRITIS OF THE KNEE

For **initial** authorization:
1. Member must be 40 years old or older; AND
2. Member must have a diagnosis of osteoarthritis confirmed by radiological evidence (e.g. Kellgren-Lawrence Scale score of grade 2 or greater); AND
3. Medication must be prescribed by an orthopedic surgeon, interventional pain physicians, rheumatologists, physiatrists (PM&R) and all sports medicine subspecialties; AND
4. Member tried and failed an intra-articular corticosteroid injection(s) in which efficacy was < 4 weeks duration; AND
5. Documentation that member tried and failed ALL of the following:
   a) Weight loss attempts or attempts at lifestyle modifications to promote weight loss (only for members with BMI ≥ 30); AND
   b) Sufficient trial (e.g. 2 to 3 months) of non-pharmacologic therapies (bracing/orthotics, physical/occupational therapy); AND
   c) At least 3 simple analgesic therapies (acetaminophen, NSAIDs, oral or topical salicylates); AND
6. Member is not using medication for hip or shoulder related conditions, AND
7. Member is not allergic to avian proteins, feathers, and egg products; AND
8. Member has tried and failed to respond to treatment with Supartz FX or Durolane or Gelsyn-3 (documented in chart notes and confirmed by claims history).
9. **Dosage allowed:** Inject 48 mg (6 mL) once.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must have documented significant pain relief that was achieved with the initial course of treatment; AND
2. Initial course of treatment has been completed for 6 months or longer; AND
3. Member meets all of the criteria for the initial approval.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource Pharmacy Policy Statement
Marketplace
Synvisc-One

CareSource considers Synvisc-One (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Refractory interstitial cystitis
- Arthropathy – Disorder of shoulder
- Intravitreal tamponade
- Keratoconjunctivitis sicca
- Subacromial impingement, Syndrome of the shoulder

References:

1. Synvisc-One [package insert]. Ridgefield, NJ: Genzyme, Inc.; January, 2010.
2. American Academy of Orthopaedic Surgeons. Treatment of Osteoarthritis of the Knee. Evidence-based guideline 2nd Edition. May 2013. Available at: http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf (December 31, 2015).
3. American College of Rheumatology, Subcommittee on Osteoarthritis Guidelines. Recommendations for the medical management of osteoarthritis of the hip and knee: 2012 update. Arthritis Care & Research 2012; 64(4):465-474. Agency for Healthcare Research and Quality (AHRQ). Three Treatments for Osteoarthritis of the Knee: Evidence Shows Lack of Benefit. Clinician's Guide. March, 2011.
4. Goldberg VM, Buckwater MD. Hyaluronans in the treatment of osteoarthritis of the knee: evidence for disease modifying activity. Osteoarthritis and Cartilage March 2005;13(3):216-224.
5. Majeed M. Relationship between serum hyaluronic acid level and disease activity in early rheumatoid arthritis. Ann Rheum Dis September 2004; 63(9): 1166-8.
6. Tascioglu F, Oner C. Efficacy of intra-articular sodium hyaluronate in the treatment of knee osteoarthritis. Clini Rheumatol. 2003;22:112-117.
7. Lo, G H, et al. JAMA. 2003;290:3115-3121. Intra-articular Hyaluronic Acid in Treatment of Knee Osteoarthritis: A Meta- analysis. Retrieved 3/17/2011 from http://jama.ama-assn.org/cgi/reprint/290/23/3115.
8. Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Viscosupplementation for the treatment of osteoarthritis of the knee. Cochrane Database Syst Rev. 2006;(2):CD005321.
9. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. Clin Orthop Relat Res. 2007; 455:113-22.
10. Synvisc-One. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 17, 2017.
11. Synvisc-One. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed May 17, 2017.
12. McGrath AF, McGrath AM, Jessop ZM, et al. A comparison of intra-articular hyaluronic acid competitors in the treatment of mild to moderate knee osteoarthritis. J Arthritis. 2013; 2(1):108. doi:10.4172/2167-7921.1000108.
13. Leighton R, Åkermark C, Therrien R, et. al. NASHA hyaluronic acid vs methylprednisolone for knee osteoarthritis: a prospective, multi-centre, randomized, non-inferiority trial. Osteoarthritis Cartilage. 2014; 22(1):17-25.

Effective date: 11/01/2019
Revised date: 11/05/2019

Update record:
11/12/2019 New Marketplace policy for Synvisc-One created

CareSource Pharmacy Policy Statement
Marketplace
Takhzyro

Drug Name: Takhzyro (lanadelumab-flyo)
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Home/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred product includes Haegarda
Quantity Limit: 2 vials (300 mg/2 ml per vial) per 30 days

Takhzyro (lanadelumab-flyo) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:

1. Member must be 12 years of age or older, and medication is being used **for routine prophylaxis to prevent HAE attacks** (NOT for treatment of acquired angioedema); AND
2. Medication prescribed by or in consultation with a provider specializing in allergy, immunology, or hematology; AND
3. Member has documented trial and failure of or contraindication to Heagarda (Chart notes required); AND
4. Member must have a confirmed diagnosis of HAE as **one** of the following:
   a) Type 1 HAE documented in chart notes with ALL of the following (*Note:* tests listed below must be repeated for confirmation of diagnosis):
      i) Low levels (below the limits of the laboratory's normal reference range) of C4, C1-INH antigenic protein and C1-INH functional level; AND
      ii) Positive family history of angioedema OR earlier age of onset (before age 30) with normal C1q antigenic protein level;
   b) Type 2 HAE documented in chart notes with ALL of the following (*Note:* tests listed below must be repeated for confirmation of diagnosis):
      i) Normal or elevated level of C1-INH antigenic protein (as defined by performing lab); AND
      ii) Low level (below the limits of the laboratory's normal reference range) C4 and C1-INH functional; AND
5. Documentation in medical chart of at least **two** attacks per month before treatment initiation; AND
6. Medication is **not** being used in combination with Haegarda; AND
7. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.
8. **Dosage allowed:** 300 mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months.

Note: Personal documentation (log book, journal, etc.) of medication use will be necessary for reauthorization. Prescribers should be aware and make their patients aware of this requirement for reauthorization.

If member meets all the requirements listed above, the medication will be approved for 3 months.

CareSource Pharmacy Policy Statement
Marketplace
Takhzyro

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member's signs and symptoms of disease have improved and the number of acute attacks per month has decreased; AND
3. Log of medication use supported by medical chart or by claims data has been provided.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Takhzyro (lanadelumab-flyo) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acquired angioedema (AAE)
- Treatment of acute HAE attacks

References:

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; November, 2018.
2. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. Allergy Asthma Clin Immunol. 2010;6(1):24.
3. ClinicalTrials.gov Identifier: NCT02586805. Efficacy and Safety Study of DX-2930 to Prevent Acute Angioedema Attacks in Patients With Type I and Type II HAE. Available at: https://clinicaltrials.gov/ct2/show/NCT02586805?term=NCT02586805&rank=1.
4. ClinicalTrials.gov Identifier: NCT02741596. Long-term Safety and Efficacy Study of DX-2930 (SHP643) to Prevent Acute Angioedema Attacks in Patients With Type I and Type II HAE. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02741596?term=NCT02741596&rank=1.
5. Craig T, Pursun EA, Bork K, Bowen T, et al. World Allergy Organization Guideline for the Management of Hereditary Angioedema. WAO J. 2012; 5:182-199.
6. Lang DM, Aberer W, Bernstein JA, et al. International consensus on hereditary and acquired angioedema. Ann Allergy Asthma Immunol. 2012;109:395-402.
7. Lumry W. Management and Prevention of Hereditary Angioedema Attacks. Am J Manag Care. 2013;19:S111-S118.

Effective date: 11/01/2019
Revised date: 08/06/2019

Update record:
11/12/2019 New Marketplace policy for Takhzyro created

CareSource Pharmacy Policy Statement
Marketplace
Ultomiris

Drug Name: Ultomiris (ravulizumab-cwvz)
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Home/Office/Outpatient
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: see **Dosage allowed** below

Ultomiris (ravulizumab-cwvz) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

For **initial** authorization:
1. Member with diagnosis of PNH as confirmed by flow cytometry (PNH type III red cells or GPI-AP-deficient polymorphonuclear cells (PMNs)); AND
2. Medication is prescribed by a hematologist or nephrologist; AND
3. Member has received vaccination against Neisseria meningitidis (i.e., Menactra®, Menveo®, MenHibrix®); AND
4. Member has LDH levels > 1.5 times the upper limit of normal documented in chart notes; AND
5. Member has one or more of the following documented in chart notes:
   a) History of at least 1 blood transfusion within the past 24 months due to anemia or anemia related symptoms or personal beliefs precluding transfusion;
   b) Presence of organ damage due to chronic hemolysis.
6. **Dosage allowed:** Administered as an IV infusion. Body weight < 60-40kg: loading dose 2,400 mg, maintenance dose 3,000 mg; body weight < 100-60 kg: loading dose 2,700 mg, maintenance dose 3,300 mg; body weight ≥ 100 mg: loading dose 3,000 mg, maintenance dose 3,600 mg.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member is stable and has shown improvement on Ultomiris.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ultomiris (ravulizumab-cwvz) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

References:

1. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc., December 2018.

2. ClinicalTrials.gov. Identifier: NCT02946463. ALXN1210 (Ravulizumab) Versus Eculizumab in Complement Inhibitor Treatment-Naïve Adult Participants With Paroxysmal Nocturnal Hemoglobinuria (PNH). Available at: https://clinicaltrials.gov/ct2/show/NCT02946463?term=ravulizumab&rank=2.
3. ClinicalTrials.gov. Identifier: NCT03056040. ALXN1210 Versus Eculizumab in Adult Participants With Paroxysmal Nocturnal Hemoglobinuria (PNH) Currently Treated With Eculizumab. Available at: https://clinicaltrials.gov/ct2/show/NCT03056040?term=ravulizumab&rank=3.
4. Lee JW, et al. Ravulizumab (ALXN1210) vs eculizumab in adult patients with PNH naive to complement inhibitors: the 301 study. Blood. 2019;133(6):530.

Effective date: 11/01/2019
Revised date: 05/07/2019

Update record:
11/12/2019 New Marketplace policy for Ultomiris created

CareSource Pharmacy Policy Statement
Marketplace
Varubi

Drug Name: Varubi (rolapitant)
Billing Code: J8670
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient Hospital/Home
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include ondansetron and promethazine
Quantity Limit: See **Dosage allowed** below

Varubi (rolapitant) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PREVENTION OF NAUSEA AND VOMITING

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Medication is being used in combination with a serotonin (5-HT3) receptor antagonist **and** dexamethasone in all members receiving highly or moderately emetogenic chemotherapy regimens including carboplatin (AUC ≥ 4)-containing regimens; AND
3. Member has tried and failed to respond to treatment with at least **two** preferred formulary agents for highly or moderately emetogenic chemotherapy (Chart notes or pharmacy claims required).
4. **Dosage allowed:** The recommended dosage for tablet form is 180 mg as a single dose. The recommended dosage for injectable emulsion is 166.5 mg administered as an intravenous infusion over 30 minutes. Medication must be administered prior to the initiation of each chemotherapy cycle, but at **no less than 2 week intervals**.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Varubi (rolapitant) not medically necessary for the treatment of the diseases that are not listed in this document.

References:

1. Varubi [package insert]. Waltham, MA; Tesaro, Inc: October, 2017.
2. Berger MJ, Ettinger DS, Aston J, et al. NCCN Guidelines® Insights. Antiemesis, Version 2.2017. Featured Updates to the NCCN Guidelines. Natl Compr Canc Netw 2017;15(7):883–893. doi:10.6004/jnccn.2017.0117.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Version 2.2017 – March 28, 2017. https://www.nccn.org/professionals/physician_gls/PDF/antiemesis.pdf.

Effective date: 11/01/2019
Revised date: 01/08/2018

CareSource Pharmacy Policy Statement
Marketplace
Varubi

Update record:
11/12/2019 New Marketplace policy for Varubi created

CareSource Pharmacy Policy Statement
Marketplace
Xeomin

Drug Name: Xeomin (incobotulinumtoxinA)
Billing Code: J0588
Benefit Type: Medical
Site of Service Allowed: Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: Up to 600 Units per treatment

Xeomin (incobotulinumtoxinA) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

BLEPHAROSPASM

For **initial** authorization:
1. Member is 18 years of age or older with diagnosis of blepharospasm, as indicated by **one** or more of the following:
   a) Benign essential blepharospasm;
   b) Blepharospasm associated with dystonia;
   c) Blepharospasm associated with facial nerve (cranial nerve VII) disorders such as Bell palsy; AND
2. Member does **not** have neuromuscular disease (e.g., myasthenia gravis).
3. **Dosage allowed:** The total initial dose of Xeomin in both eyes should not exceed 70 Units (35 Units/eye). The maximum dose per eye: 10 - 50 Units.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

For **initial** authorization:
1. Member has a pain or abnormal head position with documented turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis) causing adverse effect on daily functioning; AND
2. Member has tried and failed one oral medication such as trihexyphenidyl (Artane), clonazepam (Klonopin), or baclofen; AND
3. Member does **not** have any of the following:
   a) Fixed contractures causing decreased neck range of motion;
   b) Neuromuscular disease (e.g., myasthenia gravis);
   c) Prior surgical treatment.
4. **Dosage allowed:** 300 Units.

CareSource Pharmacy Policy Statement
Marketplace
Xeomin

If member meets all the requirements listed above, the medication will be approved for 6 months.

CHRONIC SIALORRHEA

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Member has chronic sialorrhea resulting from Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury, that was present for at least three months (chart notes required); AND
3. Member does **not** have any of the following:
   a) A history of aspiration pneumonia, amyotrophic lateral sclerosis, salivary gland or duct malformation, and gastroesophageal reflux disease;
   b) Bleeding disorders or is currently on anticoagulants;
   c) Pregnancy.
4. **Dosage allowed:** The recommended total dose is 100 Units per treatment session consisting of 30 Units per parotid gland and 20 Units per submandibular gland.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SPASTICITY (Upper Limb Only)

For **initial** authorization:
1. Member has confirmed diagnosis of post-stroke spasticity of the upper limb (at least six months post-stroke); AND
2. Chart notes submitted with documentation of abnormal muscle tone that is interfering with functional ability (or that is expected to affect joint contracture in future growth); AND
3. Medication is being requested to improve function or allow additional therapeutic modality to be employed.
4. **Dosage allowed:** Vary 5-100 Units given in divided doses among affected muscles.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Xeomin (incobotulinumtoxinA) not medically necessary for the treatment of the following disease states based on a lack of robust

clinical controlled trials showing superior efficacy compared to currently available treatments:

- Glabellar Lines (considered cosmetic)
- Tension headache, cervicogenic headache
- Myofascial pain syndrome
- Tremors such as benign essential tremor, chronic motor tic disorder and tics associated with Tourette Syndrome
- Parkinson's disease

References:

1. Xeomin [package insert].Greensboro, NC: Merz Pharmaceuticals, LLC; August 2011.
2. Brashear A, Lew MF, Dykstra DD, et al, “Safety and Efficacy of NeuroBloc (Botulinum Toxin Type B) in Type A-Responsive Cervical Dystonia,” Neurology, 1999, 53(7):1439-46.
3. Clinical Use of Botulinum Toxin,” Arch Neurol, 1991, 48(12):1294-8.
4. Benecke R, Jost WH, Kanovsky P, et al, “A New Botulinum Toxin Type A Free of Complexing Proteins for Treatment of Dystonia,” Neurology, 2005, 64(11):1949-51.
5. Borodic GE and Pearce LB, “New Concepts in Botulinum Toxin Therapy,” Drug Saf, 1994, 11(3):145-52. Jankovic J and BrinMF, “Therapeutic Uses of Botulinum Toxin,” N Engl J Med,1991, 324(17):1186-94.
6. Naumann M and Jankovic J, "Safety of Botulinum Toxin Type A: A Systematic Review and Meta-Analysis," Curr Med Res Opin, 2004, 20(7):981-90.
7. Russman, BS, Tilton, A, Gormley ME. Jr. Cerebral palsy; a rational approach to a treatment protocol, and the role of botulinum toxin in treatment, Muscle Nerve Suppl 1997; 6:S181.
8. Fishman LM, Anderson C, Rosner B. Botox and physical therapy in the treatment of Piriformis syndrome Am J Phys Med Rehabil. 2002 Dec;81(12):936-42.
9. Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. http://www.guideline.gov/content.aspx?id=12947(March11, 2011).
10. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academyof Neurology. http://www.guideline.gov/content.aspx?id=12942(March112011).
11. Simpson DM, et al. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. Neurology. 2008;70(19):1699-706.
12. Neumann M, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain. Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. Neurology. 2008; 70:1707-14.
13. Keam SJ, Muir VJ, Deeks ED. Botulinum toxin A (Dysport): in dystonias and focal spasticity. Drugs 2011;71(8):1043-58.
14. Ondo WG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson’s disease. Neurology. 2004;62(1):37-40.
15. Simpson DM, et al. Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
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CareSource Pharmacy Policy Statement
Marketplace
Xeomin

Update record:
11/12/2019 New Marketplace policy for Xeomin created

CareSource Pharmacy Policy Statement
Marketplace
Xolair

Drug Name: Xolair (omalizumab)
Billing Code: J2357 (1 unit = 5 mg)
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: 375 mg or 75 units

Xolair (omalizumab) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CHRONIC IDIOPATHIC URTICARIA (CIU)

For **initial** authorization:
1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by or under the recommendation of a dermatologist or allergist; AND
3. Member has documented weekly urticaria activity score (UAS7) of ≥ 16, and a weekly itch severity score of ≥ 8 for the 7 days; AND
4. Member has had a 3 to 10-day trial of oral corticosteroids (prednisone or prednisolone, up to 1 mg per kg per day); AND
5. Member has tried and failed hydroxyzine or doxepin for at least 14 days; AND
6. Member has tried and failed a second generation antihistamine at the maximal FDA-approved dosage for at least 14 days; AND
7. Member has tried and failed **one** of the following:
   a) Two second generation antihistamines given at the same time;
   b) A second generation antihistamine and a H2 antagonist given at the same time;
   c) A second generation antihistamine and a leukotriene receptor antagonist;
   d) The member tried and failed a second generation antihistamine and a first generation antihistamine given at the same time.
8. **Dosage allowed:** 150 or 300 mg by subcutaneous injection every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided with documented weekly UAS7 improvement.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

MODERATE TO SEVERE PERSISTENT ASTHMA

For **initial** authorization:
1. Member must be 6 years of age or older with moderate to severe persistent allergic asthma; AND
2. Medication must be prescribed by a pulmonologist, immunologist or allergist for the diagnosis of asthma; AND

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Marketplace
Xolair

3. Member has Forced Expiratory Volume in 1 second (FEV1) less than 80% predicted, or detailed assessment of signs and symptoms of moderate to severe persistent asthma from provider with detailed description of why FEV1 was unable to be obtained with; AND
4. Medication is not being used as monotherapy for asthma; AND
5. Member has a baseline plasma immunoglobulin E (IgE) level above 30 IU/mL; AND
6. Member's asthma has been inadequately controlled after 3 month of conventional treatment including **one** of the following:
   a) Medium to high doses of inhaled corticosteroids and long acting beta 2-agonists;
   b) High dose inhaled corticosteroid and a Leukotriene Receptor Antagonists; AND
7. Member has allergy testing performed, as indicated by:
   a) Positive skin testing for perennial aeroallergen; AND/OR
   b) Reactivity to at least one aeroallergen documented by elevated serum IgE level.
8. **Dosage allowed:** 75 to 375 mg by subcutaneous injection every 2 or 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

For **reauthorization**:
1. Medication is not being used as monotherapy for asthma; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has demonstrated improvement during 16 weeks of medication therapy:
   a) Decreased frequency of emergency department visits; OR
   b) Decreased frequency of hospitalizations due to asthma symptoms; OR
   c) Increase in percent predicted FEV1 from pretreatment baseline; OR
   d) Improved functional ability (i.e. decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
   e) Decreased utilization of rescue medications.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Xolair (omalizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Allergic broncho-pulmonary aspergillosis
- Allergic conditions without asthma
- Atopic dermatitis
- Allergic rhinitis
- Bullous pemphigoid
- Cholinergic urticaria and urticaria of other known causes
- Eosinophilic esophagitis
- Eosinophilic gastroenteritis
- Eosinophilic pneumonia
- Food allergy (e.g. peanut allergy)
- Initial therapy for allergic asthma

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Marketplace
Xolair

- Insulin allergy
- Latex allergy
- Nasal polyposis
- Non-allergic (non-atopic) asthma
- Subcutaneous immunotherapy, adjunct
- Vibratory angioedema

References:

1. Xolair [package insert]. South San Francisco, CA: GenetechUSA, Inc; 2016. Accessed March 2, 2017.
2. Xolair. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 2, 2017.
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4. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. J Allergy Clin Immunol. 2003;111(2):278-284.
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Revised date: 05/18/2017

Update record:
11/12/2019 New Marketplace policy for Xolair created

CareSource Pharmacy Policy Statement
Marketplace
Yescarta

Drug Name: Yescarta (axicabtagene ciloleucel)
Billing Code: Q2041
Benefit Type: Medical
Site of Service Allowed: Outpatient/Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: See **Dosage allowed** below

Yescarta (axicabtagene ciloleucel) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

LARGE B-CELL LYMPHOMA – for autologous use only

For **initial** authorization:

1. Medication is being use for adult member with relapsed or refractory large B-cell lymphoma (diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma); AND
2. Member has relapsed/refractory transplant ineligible disease, documented in chart notes and defined as **one** or more of the following:
   a) No response to first (primary refractory disease), second or greater lines of therapy;
   b) Relapsed after autologous hematopoietic stem cell transplantation (HSCT);
   c) Relapsed transplant ineligible disease; AND
3. Member must have received adequate prior therapy including at a minimum **both** of the following:
   a) Anti-CD20 monoclonal antibody (unless tumor is CD20 negative);
   b) An anthracycline containing chemotherapy regimen; AND
4. Member received the lymphodepleting regimen (cyclophosphamide 500 mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously, both given on the fifth, fourth, and third day before Yescarta); AND
5. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (leukapheresis); AND
6. Healthcare facility/provider has enrolled in the Yescarta REMS and has training on the management of cytokine release syndrome (CRS) and neurological toxicities; AND
7. Member must be premedicated with acetaminophen and an H1-antihistamine, and tocilizumab (Actemra) must be available in healthcare facility prior to infusion; AND
8. Member does **not** have history of ANY of the following:
   a) Severe, immediate hypersensitivity reaction attributed to aminoglycosides;
   b) Prior allogeneic HSCT;
   c) History or presence of primary CNS lymphoma and/or CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement;
   d) HIV infection or acute or chronic active hepatitis B or hepatitis C infection;
   e) Malignancy other than nonmelanoma skin cancer or carcinoma in situ (e.g., cervix, bladder, breast) or follicular lymphoma unless disease free for at least 3 years.
9. **Dosage allowed:** 2 □ 10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2 □ 10^8 CAR-positive viable T cells.

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Marketplace
Yescarta

Note: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
Yescarta will not be reauthorized for continued therapy.

CareSource considers Yescarta (axicabtagene ciloleucel) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Primary central nervous system lymphoma

References:
1. Yescarta [package insert]. Santa Monica, CA; Kite Pharma, Inc., October 2017. Accessed October 2017.
2. The Leukemia & Lymphoma Society (LLS). Ph-Positive ALL Therapy. Available at https://www.lls.org/leukemia/acute-lymphoblastic-leukemia/treatment/ph-positive-all-therapy.
3. ClinicalTrials.gov. Identifier NCT03153462. Axicabtagene Ciloleucel Expanded Access Study (ZUMA-9). Available at https://clinicaltrials.gov/ct2/show/NCT03153462?term=axicabtagene&rank=1. Accessed in October, 2017.
4. NCCN Guidelines. Non-Hodgkins Lymphoma. V.4.2018.
5. Neelapu SS, et al. Axicabtagene ciloleucel CAR T-cell therapy in refractory large B-cell lymphoma. N Engl J Med. 2017;377(26):2531-2544.

Effective date: 11/01/2019
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Update record:
11/12/2019 New Marketplace policy for Yescarta created

CareSource Pharmacy Policy Statement
Marketplace
Zarxio

Drug Name: Zarxio (filgrastim-sndz)
Billing Code: For medical - Q5101; for Rx - must use valid NDC
Benefit Type: Medical or Pharmacy
Site of Service Allowed: Home/Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: N/A

Zarxio (filgrastim-sndz) is a **preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ACUTE MYELOID LEUKEMIA

For **initial** authorization:
1. Member has diagnosis of AML documented in chart notes; AND
2. Medication is being used to reduce the time to neutrophil recovery and the duration of fever following induction or consolidation chemotherapy treatment; AND
3. Medication is being administered 24 hours after the last dose of chemotherapy until neutrophil recovery (ANC ≥ 1000/mm^3 for 3 consecutive days or ≥ 10,000/mm^3 for 1 day) or for a maximum of 35 days; AND
4. Chart notes with the length of chemotherapy cycle, the days of the cycle on which chemotherapy will be administered, and the days of the cycle on which Zarxio will be administered are submitted with the prior authorization request.
5. **Dosage allowed:** 5 mcg/kg/day subcutaneous injection, short intravenous infusion (15 to 30 minutes), or continuous intravenous infusion.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Member must be in compliance with all initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Zarxio therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

AUTOLOGOUS BONE MARROW TRANSPLANT (BMT)

For **initial** authorization:
1. Member has diagnosis of non-myeloid malignancy and is undergoing myeloablative chemotherapy followed by autologous BMT; AND
2. Medication is being used to reduce duration of neutropenia following autologous BMT.
3. **Dosage allowed:** 10 mcg/kg/day beginning at least 24 hours after cytotoxic chemotherapy and 24 hours after bone marrow infusion.

If member meets all the requirements listed above, the medication will be approved for 3 months.

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Marketplace
Zarxio

For **reauthorization**:
1. Member must be in compliance with all initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Zarxio therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

AUTOLOGOUS PERIPHERAL BLOOD PROGENITOR CELL (PBPC) MOBILIZATION

For **initial** authorization:
1. Medication is being used to mobilize autologous peripheral blood progenitor cells for collection by leukapheresis; AND
2. Medication is being administered for at least 4 days before first leukapheresis and continued until the last leukapheresis (until a sustainable ANC (≥ 1000/mm^3) is reached).
3. **Dosage allowed:** 10 mcg/kg/day subcutaneous injection.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Member must be in compliance with all initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Zarxio therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PREVENTION OF FEBRILE NEUTROPENIA

For **initial** authorization:
1. Member has a non-myeloid malignancy; AND
2. Medication will not be administered within 24 hours before or after chemotherapy; AND
3. Chart notes with the length of chemotherapy cycle, the days of the cycle on which chemotherapy will be administered, and the days of the cycle on which Zarxio will be administered are submitted with the prior authorization request; AND
4. Member is receiving myelosuppressive chemotherapy and has a history of febrile neutropenia (defined as an ANC < 1000/mm^3 and temperature > 38.2°C) following a previous course of chemotherapy; OR
5. Member is receiving a myelosuppressive chemotherapy regimen that is associated with a high risk (>20%) of febrile neutropenia; OR
6. Member is receiving a myelosuppressive chemotherapy regimen that is associated with an intermediate risk (10-20%) of febrile neutropenia AND has at least **one** of the following risk factors:
   a) Prior chemotherapy or radiation therapy;
   b) Persistent neutropenia;
   c) Tumor involving the bone marrow;
   d) Recent surgery and/or open wounds;
   e) Liver dysfunction (i.e. documented bilirubin >2.0);
   f) Renal dysfunction (i.e. documented creatinine clearance <50 mL/min);
   g) Age >65 years receiving full intensity dose of chemotherapy.

7. **Dosage allowed:** 5 mcg/kg per day.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Zarxio therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SEVERE CHRONIC NEUTROPENIA

For **initial** authorization:
1. Member has a history of SCN (i.e. congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia) with chart notes confirming **both** of the following:
   a) Absolute neutrophil count (ANC) < 500/mm^3 on three occasions during a 6 month period (or for cyclic neutropenia 5 consecutive days of ANC < 500/mm^3 per cycle); AND
   b) Member must have experienced a clinically significant infection during the previous 12 months.
2. **Dosage allowed:** Idiopathic neutropenia: 5 mcg/kg per day as a single dose; Cyclic neutropenia: 5 mcg/kg per day as a single dose; Congenital neutropenia: 6 mcg/kg per day in 2 divided doses.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Zarxio therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Zarxio (filgrastim-sndz) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Agranulocytosis
- AIDS - Neutropenia
- Aplastic anemia
- Febrile neutropenia
- Febrile neutropenia, In myeloid malignancies following bone marrow transplant; Prophylaxis
- Hematopoietic Syndrome of Acute Radiation Syndrome
- Infectious disease; Prophylaxis
- Leukemia
- Myelodysplastic syndrome

CareSource Pharmacy Policy Statement
Marketplace
Zarxio

- Neutropenia - Pre-eclampsia

References:

1. Zarxio (filgrastim-sndz) [prescribing information]. Princeton, NJ: Sandoz Inc; March 2016.
2. Schmitz N, Linch DC. Randomised trial of filgrastim-mobilized peripheral blood progenitor cell transplantation versus autologous bone-marrow transplantation in lymphoma patients. *Lancet*. 1996;347(8998): 353-358. Doi: 10.1016/S0140-6736(96)90536-X.
3. Blackwell K, Semiglazov V, Krasnozhon D, et al. Comparison of EP2006, a filgrastim biosimilar, to the reference: a phase III, randomized, double-blind clinical study in the prevention of severe neutropenia in patients with breast cancer receiving myelosuppressive chemotherapy. *Ann Oncol.* 2015;26:1948-1953. Doi: 10.1093/annonc/mdv281.
4. Dale DC, Bonilla MA, Davis MW, et al. A randomized controlled phase III trial of recombinant human granulocyte colony-stimulating factor (filgrastim) for treatment of severe chronic neutropenia. 1993;81(10):2496-2502.
5. Crawford J, Becker PS, Armitage JO, et al. Myeloid growth factors. NCCN Clinical Practice Guidelines in Oncology. Available from www.nccn.org. Published April 28, 2017. Accessed July 27, 2017.
6. Harada K, Yamada Y, Konishi T, et al. Comparison of transplant outcomes and economic costs between biosimilar and originator filgrastim in allogeneic hematopoietic stem cell transplantation. *Int J Hematol*. 2016;104:709-719. Doi: 10.1007/s/12185-016-2085-0.
7. Radiation Emergency Medical Management. Myeloid cytokines for acute exposure to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). U.S. Department of Health and Human Services. Available from https://www.remm.nlm.gov/cytokines.htm. Updated February 22, 2017. Accessed July 27, 2017.
8. Filgrastim-sndz. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 15, 2017.

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Update record:
11/12/2019 New Marketplace policy for Zarxio created

CareSource Pharmacy Policy Statement
Marketplace
Zulresso

Drug Name: Zulresso (brexanolone)
Billing Code: J3490
Benefit Type: Medical
Site of Service Allowed: TBD
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: See **Dosage allowed** below

Zulresso (brexanolone) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

POSTPARTUM DEPRESSION (PPD)

For **initial** authorization:
1. Member is 18 years old or older and ≤ 6 months postpartum; AND
2. Member has diagnosis of PPD and has documented onset of symptoms in the third trimester or within 4 weeks of delivery; AND
3. Member must have ceased lactating before drug administration, or if still lactating or actively breastfeeding, agreed to temporarily cease giving breastmilk to their infant(s); AND
4. Medication must be prescribed by or in consultation with psychiatrist, ob/gyn provider; AND
5. Member has documented total baseline score of Hamilton Rating Scale for Depression ≥ 20; AND
6. Member does **not** have ANY of the following:
   a) Active psychosis,
   b) Attempted suicide associated with index case of postpartum depression,
   c) Medical history of bipolar disorders, schizophrenia, and/or schizoaffective disorder.
7. **Dosage allowed:** Infusion over a total of 60 hours (2.5 days) as follows:
   0 to 4 hours: Initiate with a dosage of 30 mcg/kg/hour,
   4 to 24 hours: Increase dosage to 60 mcg/kg/hour,
   24 to 52 hours: Increase dosage to 90 mcg/kg/hour (a reduction in dosage to 60 mcg/kg/hour may be considered during this time period for patients who do not tolerate 90 mcg/kg/hour),
   52 to 56 hours: Decrease dosage to 60 mcg/kg/hour,
   56 to 60 hours: Decrease dosage to 30 mcg/kg/hour.

If member meets all the requirements listed above, the medication will be approved for 1 month.

For **reauthorization**:
1. Zulresso will not be authorized for continued administration; it is a single time injection.

CareSource considers Zulresso (brexanolone) not medically necessary for the treatment of the diseases that are not listed in this document.

References:

1. Zulresso [prescribing information]. Cambridge, MA: Sage Therapeutics, Inc.; June 2019.
2. ClinicalTrials.gov Identifier: NCT02942004. A Study to Evaluate Efficacy and Safety of SAGE-547 in Participants With Severe Postpartum Depression (547-PPD-202B). Available at: https://clinicaltrials.gov/ct2/show/NCT02942004?term=NCT02942004&rank=1.

3. ClinicalTrials.gov Identifier: NCT02942017. A Study to Evaluate Safety and Efficacy of SAGE-547 in Participants With Moderate Postpartum Depression (547-PPD-202C). Available at: https://clinicaltrials.gov/ct2/show/NCT02942017?term=NCT02942017&rank=1.
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11/12/2019 New Marketplace policy for Zulresso created