CareSource Pharmacy Policy Statement
Marketplace
Amevive (alefacept)

Billing Code: J0215 (1 unit = 0.5 mg)
Benefit Type: Medical
Site of Service Allowed: Outpatient/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Cimzia, Cosentyx, Enbrel, Otezla, and Siliq
Quantity Limit: 60 mg per 30 days

Amevive (alefacept) 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.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by a rheumatologist or dermatologist; AND
3. Member's CD4 count is documented in chart notes, and it is greater than 250 cells/microliter; AND
4. Member has moderate to severe chronic PsO for one year or over, and it involves 10% or more of the body surface area (BSA); AND
5. Member's baseline of Psoriasis Area and Severity Index (PASI) score documented in chart notes; AND
6. 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
7. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
8. 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.
9. **Dosage allowed:** IV: 7.5 mg once weekly for 12 weeks; IM: 15 mg once weekly for 12 weeks.

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 improving signs and symptoms of disease; AND
3. Member's CD4 count is greater than 250 cells/microliter; AND
4. PASI score improvement of 50% from baseline documented in chart notes.

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

CareSource considers Amevive (alefacept) not medically necessary for the treatment of the following disease states based on a lack of robust clinical

CareSource Pharmacy Policy Statement
Marketplace
Amevive (alefacept)

controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Ankylosing spondylitis
- Asthma
- Cellulitis
- Crohn's Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Psoriatic arthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Rheumatoid arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Vogt-Koyanagi

References:

1. Amevive [package insert]. Astellas Pharma US, Inc: Deerfield, IL; May, 2011.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. Journal of the American Academy of Dermatology, Volume 65, Issue 1, 137 – 174.
3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
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5. Krueger GG, Papp KA, Stough DB, et al. A randomized, double-blind, placebo-controlled phase III study evaluating efficacy and tolerability of 2 courses of alefacept in patients with chronic plaque psoriasis. J Am Acad Dermatol 2002;47:821-833.
6. Lebwohl M, Christophers E, Langley R, et al. An international, randomized, double-blind, placebo controlled phase 3 trial of intramuscular alefacept in patients with chronic plaque psoriasis. Arch Dermatol 2003;139(6):791-793.
7. Gottlieb AB, et al. Safety observations in 12095 patients with psoriasis enrolled in an international registry (PSOLAR): experience with infliximab and other systemic and biologic therapies. J Drugs Dermatol. 2014 Dec;13(12):1441-8.
8. Sbidian E, et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network metaanalysis. Cochrane Database Syst Rev. 2017;12:CD011535.
9. Nast A, et al. European S3-Guideline on the systemic treatment of psoriasis vulgaris – Update Apremilast and Secukinumab - EDF in cooperation with EADV and IPC. J Eur Acad Dermatol Venereol. 2017;31(12):1951.

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Effective date: 04/01/2019
Revised date: 02/26/2019

Update record:

11/12/2019	New Marketplace policy for Amevive created

CareSource Pharmacy Policy Statement
Marketplace
Antihemophilic Agents

Drug Names: Advate, Adynovate, Afstyla, Alphanate and Alphanate/VWF Complex/Human, AlphaNine SD, Alprolix, Bebulin and Bebulin VH, BeneFIX, Coagadex, Corifact, Eloctate, Esperoct, Factor VIII SD (Human), Feiba, Feiba NF, and Feiba VH Immuno, Fibryga, Helixate and Helixate FS, Hemlibra, Hemofil M, Humate-P and Humate-P Human, Idelvion, Ixinity, Jivi, Kcentra, Koate, Koate-DVI, and Koate-HP, Kogenate, Kogenate FS, and Kogenate FS Bio-Set, Kovaltry, Monoclate-P, Mononine, Novoeight, NovoSeven and NovoSeven RT, Nuwiq, Obizur, Profilnine and Profilnine SD, Rebinyn, Recombinate, RiaSTAP, Rixubis, Tretten, Vonvendi, Wilate, Xyntha and Xyntha Solofuse
Billing Code: J7170-Hemlibra; J7192-Advate, Helixate, Kogenate, Recombinate; J7190-Hemofil M, Koate, Monoclate-P; J7193-Alphanate, Mononine; J7194-Bebulin, Profilnine; J7195-BeneFIX, Ixinity; J7175-Coagadex; J7177-Fibryga; J7178-RiaSTAP; J7179-Vonvendi; J7180-Corifact; J7181-Tretten; J7182-Novoeight; J7183-Wilate; J7185-Xyntha; J7186-Alphanate; J7187-Humate-P; J7188-Obizur; J7189-NovoSeven; J7198-Feiba; J7200-Rixubis; J7201-Alpolix; J7202-Idelvion; J7205-Eloctate; J7207-Adynovate; J7209-Nuwiq; J7210-Afstyla; J7211-Kovaltry; J3590-Kcentra; J7199-Jivi; J7203 and J7199-Rebinyn; J7199-Esperoct
Benefit Type: Medical
Site of Service Allowed: Office/Home
Coverage Requirements: Prior Authorization Required
Alternative preferred products include <alternate drug names>
Quantity Limit: See package insert for each individual drug.

All antihemophilic agents 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.

HEMOPHILIA

For **initial** authorization:
1. Member has diagnosis of Hemophilia A or Hemophilia B; AND
2. Member's weight in kilograms, measured within the last 180 days, is documented on medication prior authorization request.
3. **Dosage allowed:** Per package insert of individual drug.

Notes: Documented diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes. Refer to the product package insert for dosing, administration and safety guidelines.

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

For **reauthorization**:
1. Member's updated measurement of weight in kilograms is documented on medication prior authorization request; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

CareSource Pharmacy Policy Statement
Marketplace
Antihemophilic Agents

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

CareSource considers antihemophilic agents not medically necessary for the treatment of the diseases that are not listed in this document.

References:

1. National Institutes of Health. National Heart, lung, and Blood Institute. “What is Hemophilia?” Available at: https://www.nhlbi.nih.gov/health-topics/hemophilia.
2. Advate [package insert]. Westlake Village, CA: Baxalta US Inc; Nov 2016.
3. Adynovate [package insert]. Westlake Village, CA: Baxalta US Inc; March 2017.
4. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC; Sept 2017.
5. Alphanate [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; June 2014.
6. Alphanine SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; March 2017.
7. Alprolix [package insert]. Cambridge, MA: Biogen Inc.; November 2017.
8. Bebulin VH [package insert]. Westlake Village, CA: Baxalta US Inc; July 2012.
9. Benefix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; June 2017.
10. Coagadex [package insert]. Durham, NC: Bio Products Laboratory USA, Inc.; No date.
11. Corifact [package insert]. Kankakee, IL: CSL Behring LLC; Sept 2017.
12. Eloctate [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; Dec 2017.
13. Feiba® [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; Nov 2013.
14. Feiba® NF [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; Feb 2011.
15. Feiba® VH [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; Apr 2005
16. Helixate® FS [package insert]. Kankakee, IL: CSL Behring LLC.; May 2014.
17. Hemlibra® [package insert]. South San Francisco, CA: Genentech, Inc.; Nov 2017
18. Hemofil® M [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; April 2012.
19. Humate-P® [package insert]. Kankakee, IL: CSL Behring LLC.; Aug 2013.
20. Idelvion® [package insert]. Kankakee, IL: CSL Behring LLC.; March 2016.
21. Ixinity [package insert]. Berwyn, PA: Aptevo BioTherapeutics LLC; April 2018.
22. Kcentra® [package insert]. Kankakee, IL: CSL Behring LLC.; Dec 2013.
23. Koate-DVI® [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; Aug 2012.
24. Kogenate™ FS [package insert]. Tarrytown, NY: Bayer Healthcare; May 2014.
25. Kovaltry [package insert]. Whippany, NJ: Bayer HealthCare LLC; March 2016.
26. Monoclate-P® [package insert] Kankakee, IL: ZLB Behring LLC.; Aug 2004
27. Mononine® [package insert]. Kankakee, IL: CSL Behring LLC.; Feb 2013.
28. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2018.
29. Novoseven® RT [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S.; May 2014.
30. NuwiQ® [package insert]. Hoboken, NJ: Octapharma USA Inc.; Sept 2015.
31. Obizur® [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; Oct 2014
32. Profilnine [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; Aug 2010.
33. Rebinyn [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; May 2017.
34. Recombinate® [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; Dec 2010.
35. RiaSTAP® [package insert] Kankakee, IL: CSL Behring LLC.; Dec 2011.
36. Rixubis [package insert]. Westlake Village, CA: Baxalta US Inc.; Sept 2014.
37. Tretten® [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S.; Apr 2014.
38. VonVendi® [package insert]. Westlake Village, CA: Baxalta US Inc.; Dec 2015.
39. Wilate® [package insert]. Hoboken, NJ: Octapharma USA Inc.; Aug 2010.
40. Xyntha® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; Oct 2014.
41. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; August 2018.
42. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; February, 2019.

CareSource Pharmacy Policy Statement
Marketplace
Antihemophilic Agents

Effective date: 09/26/2019
Revised date: 08/06/2019

Update record:

11/12/2019	New Marketplace policy for antihemophilic agents created

CareSource Pharmacy Policy Statement
Marketplace
Benlysta

Drug Name: Benlysta (belimumab)
Billing Code: J0490
Benefit Type: Medical
Site of Service Allowed: Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: See **Dosage allowed** below.

Benlysta (belimumab) 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.

SYSTEMIC LUPUS ERYTHEMATOSUS

For **initial** authorization:

1. Member is 5 years of age or older; AND
2. Medication must be prescribed by a rheumatologist; AND
3. Member must have active disease with SELENA-SLEDAI score of 6 or greater (documented in chart notes) prior to initiating Benlysta; AND
4. Member is autoantibody-positive with chart notes documentation of anti-nuclear antibody (ANA) titer ≥1:80 and/or anti-double-stranded DNA (anti-dsDNA) ≥ 30 IU/mL; AND
5. Member meets ALL of the following:
   a) Member requires daily use of oral corticosteroids, unless contraindicated, or previously ineffective or not tolerated;
   b) Member has tried and failed to respond to treatment with at least **two** of the following: chloroquine, hydroxychloroquine, methotrexate, azathioprine, cyclophosphamide, or mycophenolate mofetil for at least 12 weeks;
   c) Member is not currently on intravenously administered cyclophosphamide or another biologic agent.
6. **Dosage allowed:** Intravenously (for adult and pediatric members) 10 mg/kg at 2 week intervals for first 3 doses and at 4 week intervals thereafter. Subcutaneously (only for adult members) 200 mg once weekly.

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. Member has SELENA-SLEDAI score improvement documented in chart notes; 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 Benlysta (belimumab) 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:

CareSource Pharmacy Policy Statement
Marketplace
Benlysta

- Severe active lupus nephritis
- Severe active central nervous system lupus

References:

1. Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; April, 2019.
2. FDA Briefing Document for the Arthritis Advisory Committee Meeting: Benlysta/Belimumab. November 16, 2010. Available at: http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/arthritisdrugsadvisorycommittee/ucm233579.pdf.
3. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. Arthritis Rheum. 2011; 63 (12): 3918 – 30.
4. Navarra SV, Guzman RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. Lancet. 2011; 26 (377): 721 – 31.
5. Wallace DJ, Sohl W, Furie RA, et al, A phase II, randomized, double-blind, placebo-controlled, dose-ranging study of belimumab in patients with active systemic lupus erythematosus. Arthritis Rheum. 2009; 61 (9): 1168 – 78.
6. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. Arthritis Rheum. 1999; 42 (9): 1785 – 1796.
7. Gold Standard, Inc. Benlysta. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com.
8. American College of Rheumatology. Belimumab for systemic lupus erythematosus. March 15, 2011.
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12. Petri M. Disease activity assessment in SLE: do we have the right instruments? Ann Rheum Dis. 2007; 66 (suppl III):iii61 – iii64.
13. ClinicalTrials.gov. Identifier: NCT01649765. Pediatric Lupus Trial of Belimumab Plus Background Standard Therapy (PLUTO). Available at: https://clinicaltrials.gov/ct2/show/NCT01649765?term=01649765&rank=1.

Effective date: 11/01/2019
Revised date: 07/28/2019

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

CareSource Pharmacy Policy Statement
Marketplace
Berinert

Drug Name: Berinert (C1 Esterase Inhibitor (Human))
Billing Code: J0597
Benefit Type: Medical
Site of Service Allowed: Home/Office
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: 8 vials per fill (32 vials per month)

Berinert (C1 Esterase Inhibitor (Human)) 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.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:
1. Member must be 6 years of age or older, and medication is being used **for the treatment of acute abdominal, facial, or laryngeal 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 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
4. Medication is **not** being used in combination with Kalbitor, Firazyr, or Ruconest; AND
5. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.
6. **Dosage allowed:** Dose of 20 International Units (IU) per kg body weight by intravenous injection.

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.

CareSource Pharmacy Policy Statement
Marketplace
Berinert

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

CareSource considers Berinert (C1 Esterase Inhibitor (Human)) 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:

- HAE prophylactic therapy
- Acquired angioedema (AAE)

References:

1. 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.
2. 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.
3. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; September, 2016.
4. Berinert. 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: 08/25/2017

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

CareSource Pharmacy Policy Statement
Marketplace
Boniva

Drug Name: Boniva (ibandronate) injection
Billing Code: J1740
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient hospital
Coverage Requirements: Prior Authorization Required for injectable product only (no Prior Authorization needed for oral product)
Alternative preferred products include zoledronic acid
Quantity Limit: See **Dosage allowed** below.

Boniva (ibandronate) 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.

OSTEOPOROSIS

For **initial** authorization:

1. Medication is intended to be used for treatment of osteoporosis in postmenopausal women with high risk for fracture;
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. Documentation of member's inability to take oral bisphosphonate therapies (i.e., alendronate and/or ibandronate) required 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:** IV: 3 mg every 3 months.

CareSource Pharmacy Policy Statement
Marketplace
Boniva

Note: IV form of the drug is only indicated for treatment (not prevention) of osteoporosis in postmenopausal women.

If member meets all the requirements listed above, the medication will be approved for 12 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 considers Boniva (ibandronate) 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
- Bone loss (for nonmetastatic prostate cancer or for breast cancer)

References:
1. Boniva [prescribing information]. South San Francisco, CA: Genentech, Inc.; April, 2019.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. Endocr Pract. 2016;22(Suppl 4). Doi: 10.4158/EP161435.GL.
3. Tu KN, Lie JD, Wan CKV, et al. Osteoporosis: A Review of Treatment Options. P&T. 2018 Feb; 43(2): 92–104.
4. Porter JL, Varacallo M. Osteoporosis. StatPearls Publishing LLC. Bookshelf ID: NBK441901, PMID: 28722930. Available at: https://www.researchgate.net/profile/Matthew_Varacallo/publication/329717790_Osteoporosis/links/5c17f5314585157ac1ca042b/Osteoporosis.pdf?origin=publication_detail.

Effective date: 09/26/2019
Revised date: 07/29/2019

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

CareSource Pharmacy Policy Statement
Marketplace
Brineura

Drug Name: Brineura (cerliponase alfa)
Billing Code: J3590 (1 unit = 1 mg)
Benefit Type: Medical
Site of Service Allowed: Outpatient Hospital/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: 600 mg every 28 days

Brineura (cerliponase 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.

INFANTILE NEURONAL CEROID LIPOFUSCINOSIS TYPE 2 (CLN2), aka tripeptidyl peptidase 1 (TPP1) deficiency

For **initial** authorization:
1. Medication is being used to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency; AND
2. Member is between the ages 3 and 16 years old; AND
3. Member has mild to moderate disease documented by a two-domain score of 3-6 on motor and language domains of the Hamburg Scale, with a score of at least 1 in each of these two domains; AND
4. Member does not have a score of 0 points on the combined motor and language components of the Hamburg CLN2 rating scale; AND
5. Member does not have another neurological illness that may have caused cognitive decline (e.g. trauma, meningitis, or hemorrhage); AND
6. Member does not require ventilation support; AND
7. Member does not have generalized motor status epilepticus within 4 weeks of first dose.
8. **Dosage allowed:** 300 mg administered once every other week as an intraventricular infusion followed by infusion of Intraventricular Electrolytes over approximately 4.5 hours.

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's loss of ambulation slowed and it is documented in chart notes.

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

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

References:

1. ClinicalTrials.gov. BMN 190. Available at: https://clinicaltrials.gov/ct2/results?term=bmn+190&Search=Search. Accessed January 1, 2017.

2. ClinicalTrials.gov. A phase 2 open-label study to evaluate safety, tolerability, and efficacy of intracerebroventricular BMN 190 in patients with CLN2 disease. Available at: https://clinicaltrials.gov/ct2/show/NCT02485899?term=bmn+190&rank=3. Accessed January 8, 2017.
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Effective date: 11/01/2019
Revised date: 05/17/2017

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

CareSource Pharmacy Policy Statement
Marketplace
Cinryze

Drug Name: Cinryze (C1 esterase inhibitor (human))
Billing Code: J0598
Benefit Type: Medical
Site of Service Allowed: Home/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred product includes Haegarda
Quantity Limit: 20 vials (500 IU/vial) per 30 days

Cinryze (C1 esterase inhibitor (human)) 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 6 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:** 1,000 units intravenously every 3-4 days.

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**:

CareSource Pharmacy Policy Statement
Marketplace
Cinryze

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 Cinryze (C1 esterase inhibitor (human)) 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. Cinryze [package insert]. Exton, PA; ViroPharma Biologics, Inc.; June 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.
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Effective date: 11/01/2019
Revised date: 07/27/2018

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

CareSource Pharmacy Policy Statement
Marketplace
Crysvita

Drug Name: Crysvita (burosumab-twza)
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: Up to 90 mg per month

Crysvita (burosumab-twza) 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.

X-LINKED HYPOPHOSPHATEMIA (XLH)

For **initial** authorization:
1. Member is 1 year old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist or nephrologist; AND
3. Member has diagnosis of XLH supported by ONE of the following:
   a) Confirmed Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX) mutation in the member or a directly related family member with appropriate X-linked inheritance;
   b) Serum fibroblast growth factor 23 (FGF23) level > 30 pg/mL by Kainos assay; AND
4. Member has baseline serum phosphorus concentration below the normal range for age; AND
5. Member has chart notes documentation of ONE of the following:
   a) Radiographic evidence of active bone disease including rickets in the wrists and/or knees, AND/OR femoral/tibial bowing;
   b) Rickets Severity Score (RSS) score in the knee of at least 1.5 as determined by central read; AND
6. Member does **not** have ANY of the following:
   a) Human immunodeficiency virus antibody, hepatitis B surface antigen, and/or hepatitis C antibody;
   b) History of recurrent infection or predisposition to infection, or of known immunodeficiency;
   c) Hypocalcemia or hypercalcemia, defined as serum calcium levels outside the age-adjusted normal limits; AND
7. Member does **not**:
   a) Use oral phosphate and active vitamin D analogs (contraindicated with Crysvita);
   b) Have severe renal impairment or end stage renal disease (contraindicated with Crysvita).
8. **Dosage allowed:** Adult XLH (18 years of age and older): Dose regimen is 1 mg/kg body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg administered every four weeks. Pediatric XLH (less than 18 years of age): Starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg. Dose may be increased up to approximately 2 mg/kg (maximum 90 mg), administered every two weeks to achieve normal serum phosphorus.

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

For **reauthorization**:
1. Member's serum phosphorus concentration increased from baseline; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

CareSource Pharmacy Policy Statement
Marketplace
Crysvita

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

CareSource considers Crysvita (burosumab-twza) not medically necessary for the treatment of the diseases that are not listed in this document.

References:

1. Crysvita [package insert]. Novato, CA: Ultragenyx Pharmaceutical Inc.; April, 2018.
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Effective date: 11/01/2019
Revised date: 05/16/2018

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

CareSource Pharmacy Policy Statement
Marketplace
Dysport

Drug Name: Dysport (abobotulinumtoxinA)
Billing Code: J0586
Benefit Type: Medical
Site of Service Allowed: Office, Outpatient
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: Vary per diagnosis

Dysport (abobotulinumtoxinA) 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:** 500 Units given intramuscularly as a divided dose 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.

SPASTICITY

For **initial** authorization:
1. 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
2. Medication is being requested to improve function or allow additional therapeutic modality to be employed; AND
3. One of the following:
   a) Member is a child with cerebral palsy;
   b) Member has hereditary spastic paraplegia;
   c) Member has limb spasticity due to multiple sclerosis or other demyelinating diseases of the central nervous system;

d) Member is adult and has upper extremity spasticity due to stroke or brain injury.

4. **Dosage allowed:** 500-1500 Units given intramuscularly as a divided dose 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 Dysport (abobotulinumtoxinA) 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
- Sialorrhea due to Parkinson's disease

References:

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

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

CareSource Pharmacy Policy Statement
Marketplace
Epogen

Drug Name: Epogen (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

Epogen (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
Epogen

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**:
Medication will not be reauthorized.

CareSource considers Epogen (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. Epogen [package insert]. Thousand Oaks, CA: Amgen, Inc.; 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.
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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 Epogen created

CareSource Pharmacy Policy Statement
Marketplace
Euflexxa

Drug Name: Euflexxa (sodium hyaluronate)
Billing Code: J7323
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: 3 injections (3 units)

Euflexxa (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 or Gel-One (documented in chart notes and confirmed by claims history).
8. **Dosage allowed:** Inject 20 mg (2 mL) once weekly for 3 weeks (total of 3 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 Euflexxa (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust

CareSource Pharmacy Policy Statement
Marketplace
Euflexxa

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. Euflexxa [package insert]. Parisippany, NJ: Ferring Pharmaceuticals, Inc.; July 2016.
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).
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15. Euflexxa. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed May 17, 2017.
16. 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.
17. 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

CareSource Pharmacy Policy Statement
Marketplace
Euflexxa

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

CareSource Pharmacy Policy Statement
Marketplace
Evenity

Drug Name: Evenity (romosozumab-aggg)
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include alendronate, ibandronate and zoledronic acid
Quantity Limit: 210 mg monthly for 12 months

Evenity (romosozumab-aqqg) 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 the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture (*see Appendix*), or who have failed or are intolerant to other available osteoporosis therapy; AND
2. Member's osteoporosis evidenced by one if the following:
   a) Bone mineral density (BMD) T-score –2.5 or below at the total hip or femoral neck and either one moderate or severe vertebral fracture or two mild vertebral fractures;
   b) BMD T-score less than or equal to –2.0 at the total hip or femoral neck and either two moderate or severe vertebral fractures or a history of a proximal femur fracture; AND
3. Member does **not** have ANY of the following:
   a) Uncorrected hypocalcemia;
   b) Dental disease
   c) History of hip fracture; AND
4. Member was instructed to take at least 500 mg daily of calcium and at least 600 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:** 210 mg monthly.

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

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

CareSource Pharmacy Policy Statement
Marketplace
Evenity

CareSource considers Evenity (romosozumab-aqqg) 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. Evenity [prescribing information]. Thousand Oaks, CA: Amgen Inc.; April, 2019.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. Endocr Pract. 2016;22(Suppl 4). Doi: 10.4158/EP161435.GL.
3. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012;97(6):1802-1822. Doi: 10.1210/jc.2011-3045.
4. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Rheumatol. 2017;69(8):1521-1537. Doi: 10.1002/art.40137.
5. Bienz M, Saad F. Androgen-deprivation therapy and bone loss in prostate cancer patients: a clinical review. Bonekey Rep. 2015;4:Article 716. Doi: 10.1038/bonekey.2015.85.
6. ClinicalTrials.gov. Identifier: NCT01575834. Efficacy and Safety of Romosozumab Treatment in Postmenopausal Women With Osteoporosis (FRAME). Available at: https://clinicaltrials.gov/ct2/show/NCT01575834?term=NCT01575834&rank=1.
7. Michael R. McClung, et al. Sclerostin antibodies in osteoporosis: latest evidence and therapeutic potential. Ther Adv Musculoskelet Dis. 2017 Oct; 9(10): 263-270.
8. Kristie N. Tu, et al. Osteoporosis: A Review of Treatment Options. P T. 2018 Feb; 43(2): 92-104.

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

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

CareSource Pharmacy Policy Statement
Marketplace
Exondys 51

Drug Name: Exondys 51 (eteplirsen)
Billing Code: J1428 (1 unit = 10 mg)
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient/Home
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: Based on weight

Exondys 51 (eteplirsen) 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.

DUCHENNE MUSCULAR DYSTROPHY (DMD)

For **initial** authorization:
1. Member has confirmed mutation of a DMD gene that is amenable to exon 51 skipping (chart/lab notes required); AND
2. Member is currently taking a corticosteroid or has contraindication to corticosteroids; AND
3. Chart notes submitted confirming that the member is ambulatory and walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Exondys 51 therapy.
4. **Dosage allowed:** 30 milligrams per kilogram of body weight once weekly.

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 submitted with member's status reviewed within 30 days prior to reauthorization request confirming that the member remains ambulatory and walks independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.).

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

CareSource considers Exondys 51 (eteplirsen) not medically necessary for the treatment of the diseases that are not listed in this document.

References:

1. Exondys 51 [Package Insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; September 2016.
2. Sarepta Therapeutics. An Open-Label, Multi-Center Study to Evaluate the Safety and Tolerability of Eteplirsen in Patients With Advanced Stage Duchenne Muscular Dystrophy. NLM Identifier: NCT02286947.
3. Sarepta Therapeutics. Confirmatory Study of Eteplirsen in DMD Patients (PROMOVI). NLM Identifier: NCT02255552.
4. Sarepta Therapeutics. An Open-Label, Multi-Center Study to Evaluate the Safety and Tolerability of Eteplirsen in Early Stage Duchenne Muscular Dystrophy. NLM Identifier: NCT02420379.

Effective date: 11/01/2019
Revised date: 05/20/2019

CareSource Pharmacy Policy Statement
Marketplace
Exondys 51

Update record:
11/12/2019 New Marketplace policy for Exondys 51 created

CareSource Pharmacy Policy Statement
Marketplace
Fasenra

Drug Name: Fasenra (benralizumab)
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: 30 mg/mL

Fasenra (benralizumab) 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.

SEVERE ASTHMA

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 pulmonologist, immunologist or allergist; AND
3. Member has eosinophilic phenotype as defined by a baseline (pre-benralizumab treatment) peripheral blood eosinophil level ≥ 150 cells/μL within the past 6 weeks; AND
4. Member's asthma has been inadequately controlled after 3 month of conventional treatment of medium to high doses of inhaled corticosteroids (ICS) and long acting beta 2-agonists (LABA); AND
5. Member has at least two documented severe asthma exacerbation within last year; AND
6. Medication is being used as the add-on maintenance treatment to conventional therapies for asthma (i.e., ICS, LABA, etc.); AND
7. Medication is not used in combination with Nucala (mepolizumab) or Cinqair (reslizumab).
8. **Dosage allowed:** Recommended dose is 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter.

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

For **reauthorization**:
1. Medication 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 Fasenra (benralizumab) 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 lung infection
- Acute bronchospasm
- Allergic bronchopulmonary aspergillosis/mycosis
- Alpha 1 anti-trypsin deficiency
- Atopic dermatitis
- Atopic eczema
- Bronchiectasis
- Chronic obstructive pulmonary disease
- Chronic rhinosinusitis
- Churg-Strauss syndrome
- Cystic fibrosis
- Eosinophil gastroenteritis
- Eosinophilic esophagitis
- Eosinophilic granulomatosis with polyangiitis
- Hyper-eosinophilic syndrome
- Hypoventilation syndrome associated with obesity
- Lung cancer
- Nasal polyposis
- Primary ciliary dyskinesia
- Pulmonary fibrosis
- Status asthmaticus

References:

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; November 2017.
2. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT01914757 Efficacy and Safety Study of Benralizumab in Adults and Adolescents Inadequately Controlled on Inhaled Corticosteroid Plus Long-acting □2 Agonist. Available at: https://clinicaltrials.gov/ct2/show/NCT01914757?term=benralizumab&recrs=e&draw=1&rank=6.
3. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. J Asthma Allergy. 2014;7:53–65.
4. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT02075255. Efficacy and Safety Study of Benralizumab to Reduce OCS Use in Patients With Uncontrolled Asthma on High Dose Inhaled Corticosteroid Plus LABA and Chronic OCS Therapy. Available at: https://clinicaltrials.gov/ct2/show/NCT02075255?term=benralizumab&recrs=e&draw=1&rank=7.
5. Goldman M, Hirsch I, Zangrilli JG, et al. The association between blood eosinophil count and benralizumab efficacy for patients with severe, uncontrolled asthma: subanalyses of the Phase III SIROCCO and CALIMA studies. Curr Med Res Opin. 2017 Sep;33(9):1605-1613.

Effective date: 11/01/2019
Revised date: 05/12/2018

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

CareSource Pharmacy Policy Statement
Marketplace
Firazyr

Drug Name: Firazyr (icatibant)
Billing Code: J1744
Benefit Type: Medical
Site of Service Allowed: Home/Office
Coverage Requirements: Prior Authorization Required (Preferred Product)
Alternative preferred product includes Berinert
Quantity Limit: 6 mL per fill (18 mL per 30 days)

Firazyr (icatibant) 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.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:

1. Member must be 18 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 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
4. Medication is **not** being used in combination with Kalbitor, Berinert, or Ruconest; AND
5. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.
6. **Dosage allowed:** 30 mg subcutaneously; repeat at least 6 hours later if symptoms persist. No more than 3 doses in 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.

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.

CareSource Pharmacy Policy Statement
Marketplace
Firazyr

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

CareSource considers Firazyr (icatibant) 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. Firazyr [package insert]. Lexington, MA; Shire Orphan Therapies, Inc.; August 2011.
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. Firazyr. 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: 08/25/2017

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

CareSource Pharmacy Policy Statement
Marketplace
Fulphila

Drug Name: Fulphila (pegfilgrastim-jmdb)
Billing Code: Q5108
Benefit Type: Medical
Site of Service Allowed: Home/Office/Outpatient
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred product includes Neulasta
Quantity Limit: 12 mg per 28 days

Fulphila (pegfilgrastim-jmdb) 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.

PREVENTION OF FEBRILE NEUTROPENIA

For **initial** authorization:
1. Member has a non-myeloid malignancy; AND
2. Medication will not be administered less than 14 days before OR less than 24 hours after chemotherapy; AND
3. Chart notes with length of chemotherapy cycle, the days of the cycle on which chemotherapy will be administered, and the day of the cycle on which the Fulphila will be administered, are submitted with prior authorization request; AND
4. Member has a documented history of febrile neutropenia (defined as an ANC < 1000/mm^3 and temperature > 38.2°C) following a previous course of chemotherapy and is receiving myelosuppressive chemotherapy; OR
5. Member is receiving myelosuppressive anti-cancer drugs associated with a high risk (> 20%, see Appendix for description) for incidence of febrile neutropenia; OR
6. Member is receiving myelosuppressive anti-cancer drugs associated with at intermediate risk (10-20%, see Appendix for description) for incidence of febrile neutropenia including **one** of the following:
   a) Previous chemotherapy or radiation therapy;
   b) Persistent neutropenia;
   c) Bone marrow involvement with tumor;
   d) Recent surgery and/or open wounds;
   e) Liver dysfunction (bilirubin > 2.0);
   f) Renal dysfunction (creatinine clearance < 50);
   g) Age > 65 years receiving full chemotherapy dose intensity.
7. **Dosage allowed:** Up to 6 mg per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy.

Note: Fulphila is not indicated for hematopoietic syndrome of acute radiation syndrome.

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.

CareSource Pharmacy Policy Statement
Marketplace
Fulphila

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

CareSource considers Fulphila (pegfilgrastim-jmdb) 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:

- Hematopoietic syndrome of acute radiation syndrome
- Mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplant

References:

1. Fulphila [package insert]. Rockford, IL: Mylan Institutional LLC.; June 2018.
2. U.S. Food and Drug Administration. Media release. FDA approved first biosimilar to Nulasta to help reduce the risk of infection during cancer treatment. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm609805.htm. Accessed on July 25, 2018.
3. National Comprehensive Cancer Network. (2016). NCCN Drugs & Biologics Compendium™. Pegfilgrastim. Retrieved November 22, 2016 from the National Comprehensive Cancer Network.

Effective date: 11/01/2019
Revised date: 07/25/2018

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

CareSource Pharmacy Policy Statement
Marketplace
Gel-One

Drug Name: Gel-One (sodium hyaluronate)
Billing Code: J7326
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)

Gel-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;
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 30 mg (3 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 Gel-One (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust

CareSource Pharmacy Policy Statement
Marketplace
Gel-One

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. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May, 2011.
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. Chevalier X, Jerosch J, Goupille P, et al. Single, intra-articular treatment with 6 ml hylan G-F 20 in patients with symptomatic primary osteoarthritis of the knee: a randomized, multicenter, double-blind, placebo controlled trial. Ann Rheum Dis. 2010 Jan;69(1):113-9.
5. 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.
6. Majeed M. Relationship between serum hyaluronic acid level and disease activity in early rheumatoid arthritis. Ann Rheum Dis September 2004; 63(9): 1166-8.
7. Tascioglu F, Oner C. Efficacy of intra-articular sodium hyaluronate in the treatment of knee osteoarthritis. Clini Rheumatol. 2003;22:112-117.
8. 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.
9. 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.
10. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. Clin Orthop Relat Res. 2007; 455:113-22.
11. Petrella RJ, Wakeford C. Pain relief and improved physical function in knee osteoarthritis patients receiving ongoing hylan G-F 20, a high-molecular-weight hyaluronan, versus other treatment options: data from a large real-world longitudinal cohort in Canada. Drug Des Devel Ther. 2015;9:5633-40.
12. Christensen R, Bartels EM, Astrup A, Bliddal H. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and meta-analysis. Ann Rheum Dis. 2007: 66(4):433-9.
13. Gel-One. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 17, 2017.
14. Gel-One. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed May 17, 2017.
15. 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.
16. 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: 07/01/2018
Revised date: 11/05/2019

CareSource Pharmacy Policy Statement
Marketplace
Gel-One

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

CareSource Pharmacy Policy Statement
Marketplace
GenVisc 850

Drug Name: GenVisc 850 (sodium hyaluronate)
Billing Code: J7320
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: 5 injections (125 units) - 25 billing units per injection

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GenVisc 850 (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 25 mg (2.5 mL) once weekly for 5 weeks (total of 5 injections); some patients may benefit from a total of 3 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 GenVisc 850 (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of

CareSource Pharmacy Policy Statement
Marketplace
GenVisc 850

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. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx. 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. Genvisc. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 17, 2017.
11. Genvisc. 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 GenVisc created

CareSource Pharmacy Policy Statement
Marketplace
Granix

Drug Name: Granix (tbo-filgrastim)
Billing Code: J1447
Benefit Type: Medical
Site of Service Allowed: Home/Office/Outpatient Hospital
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Zarxio
Quantity Limit: N/A

Granix (tbo-filgrastim) 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.

PREVENTION OF FEBRILE NEUTROPENIA

For **initial** authorization:
1. Member is 18 years of age or older with a non-myeloid malignancy; AND
2. Member must have tried and failed treatment with Zarxio; AND
3. Medication will not be administered within 24 hours of myelosuppressive chemotherapy and will be administered for at least 5 days until neutrophil recovery (ANC ≥1,000/mm^3) up to a maximum of 14 days; AND
4. Chart notes with length of chemotherapy cycle, the days of the cycle on which chemotherapy will be administered, and the day of the cycle on which Granix will be administered, are submitted with prior authorization request; AND
5. Member has a documented history of febrile neutropenia following a previous course of chemotherapy and is receiving myelosuppressive chemotherapy; OR
6. Member is receiving myelosuppressive anti-cancer drugs associated with a high risk (>20%, see Appendix for description) for incidence of febrile neutropenia; OR
7. Member is receiving myelosuppressive anti-cancer drugs associated with at intermediate risk (10-20%, see Appendix for description) for incidence of febrile neutropenia including **one** of the following:
   a) Previous chemotherapy or radiation therapy;
   b) Persistent neutropenia;
   c) Bone marrow involvement with tumor;
   d) Recent surgery and/or open wounds;
   e) Liver dysfunction (bilirubin >2.0);
   f) Renal dysfunction (creatinine clearance <50);
   g) Age >65 years receiving full chemotherapy dose intensity.
8. **Dosage allowed:** 5 mcg/kg per day administered as a subcutaneous injection.

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 is stable or has shown improvement on Granix therapy.

CareSource Pharmacy Policy Statement
Marketplace
Granix

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

CareSource considers Granix (tbo-filgrastim) 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 myeloid leukemia
- Hematopoietic Subsyndrome of Acute Radiation Syndrome
- Mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplant
- Myeloid recovery following autologous or allogenic bone marrow transplant
- Nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant
- Severe chronic neutropenia

References:

1. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva; February 2017.
2. Del Giglio A, Eniu A, Ganea-Motan D, Tupozov E, Lubenau H. XM02 is superior to placebo and equivalent to Neupogen in reducing the duration of severe neutropenia and the incidence of febrile neutropenia in cycle I in breast cancer patients receiving docetaxel/doxorubicin in chemotherapy. *BMC Cancer*. 2008;8:332-339. Doi: 10.1186/1471-2407-8-332.

Effective date: 11/01/2019
Revised date: 10/19/2017

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

CareSource Pharmacy Policy Statement
Marketplace
H.P. Acthar Gel

Drug Name: H.P. Acthar Gel (respiratory corticotropin injection)
Billing Code: J0800
Benefit Type: Medical
Site of Service Allowed: Home, Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Quantity Limit: Two-5mL vials per 26 days

H.P. Acthar Gel (repository corticotropin 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.

INFANTILE SPASMS (West syndrome, X-linked infantile spasms syndrome)

For **initial** authorization:
1. Member has documented diagnosis of infantile spasms; AND
2. Member is an infant or a child under 2 years of age; AND
3. Medication must be prescribed by a pediatric neurologist or an epilepsy physician specialist.
4. **Dosage allowed:** The recommended regimen is a daily dose of 150 U/m^2 (divided into twice daily intramuscular injections of 75 U/m^2) administered over a 2-week period.

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

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 1 month.

CareSource considers H.P. Acthar Gel (repository corticotropin injection) 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:

- Corticosteroid-responsive conditions (e.g., systemic lupus erythematosus, multiple sclerosis, Stevens-Johnson's syndrome, ophthalmic diseases, rheumatic disorders, serum sickness, and symptomatic sarcoidosis) as it has not been proven to be any more effective than corticosteroids for these indications
- All other uses of H.P. Acthar Gel (e.g., acute gout, childhood epilepsy, and use in tobacco cessation) are considered experimental/investigational

References:

1. H.P. Acthar Gel [package insert]. Hazelwood, MO: Mallinckrodt ARD Inc.; July, 2017.
2. AAN/CNS evidence-based guideline update on medical treatment of infantile spasms. Neurology 2012: 78 (24): 1974 – 80. doi: 10.1212/WNL.0b013e318259e2cf.

3. Gold Standard, Inc. Corticotropin ACTH. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc; 2012. Available from: http://www.clinicalpharmacology.com.
4. Management and prognosis of infantile spasms. Daniel G Glaze. UpToDate [online database]. Available from: http://www.uptodate.com
5. Milanese C, La Mantia L, Salmaggi A, et al. Double-blind randomized trial of ACTH versus dexamethasone versus methylprednisolone in multiple sclerosis bouts. Clinical, cerebrospinal fluid and neurophysiological results. Eur Neurol. 1989; 29 (1): 10 – 14.
6. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology. 1989; 39 (7): 969 – 971.
7. Simsarian JP, Saunders C, Smith DM. Five-day regimen of intramuscular or subcutaneous self-prospective, randomized, open-label pilot trial. Drug Des Devel Ther. 2011; 5:381 – 389.
8. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. Drug Des Devel Ther. 2011; 5:147 – 153.
9. 1Go CY, Mackay MT, Weiss SK, Stephens D, Adams-Webber T, Ashwal S, Snead, III OC. Evidence-based guideline update: Medical treatment of infantile spasms. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. Neurology. 2012; 78(24): 1974 – 1980.
10. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. Cochrane Database Syst Rev. 2013.
11. French JA, Mosier M, Walker S, et al. A double-blind, placebo-controlled study of vigabatrin (3 g/day) in patients with uncontrolled complex partial seizures. Vigabatrin Protocol 024 Investigative Cohort. Neurology 1996;46(1):54-61.
12. Dean C, Mosier M, Penry K. Dose-response study of vigabatrin as add-on therapy in patients with uncontrolled complex partial seizures. Epilepsia. 1999;40(1):74-82.

Effective date: 11/01/2019
Revised date: 10/08/2018

Update record:
11/12/2019 New Marketplace policy for H.P. Acthar created

CareSource Pharmacy Policy Statement
Marketplace
Haegarda

Drug Name: Haegarda (C1 inhibitor (human))
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Home/Office
Coverage Requirements: Prior Authorization Required (Preferred Product)
Quantity Limit: 60 units/kg of actual body weight twice weekly

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Haegarda (C1 inhibitor (human)) 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.

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 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
4. Documentation in medical chart of at least **two** attacks per month before treatment initiation; AND
5. Medication is **not** being used in combination with Cinryze; 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:** 60 units/kg of actual body weight twice weekly.

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'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 Haegarda (C1 inhibitor (human)) 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. 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.
2. ClinicalTrials.gov web site. Bethesda, MD. U.S. National Institutes of Health. Identifier NCT02584959, Study to Evaluate the Clinical Efficacy and Safety of Subcutaneously Administered C1 Esterase Inhibitor for the Prevention of Angioedema Attacks in Adolescents and Adults With Hereditary Angioedema; October 20, 2015. Available at: https://clinicaltrials.gov/ct2/show/NCT02584959.
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4. Haegarda (C1 Esterase Inhibitor [Human]) [prescribing information]. Kankakee, IL: CSL Behring LLC; June 2017.
5. Lang DM, Aberer W, Bernstein JA, et al. International consensus on hereditary and acquired angioedema. Ann Allergy Asthma Immunol. 2012;109:395-402.
6. Lexicomp Online® , Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc.; July 17, 2017.
7. Longhurst H, Cicardi M, Craig T, et al. Prevention of Hereditary Angioedema Attacks with a Subcutaneous C1 Inhibitor. N Engl J Med. 2017;376(12):1131-1140.
8. Lumry W. Management and Prevention of Hereditary Angioedema Attacks. Am J Manag Care. 2013;19:S111-S118.
9. Haegarda. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed August 8, 2017.
10. Zuraw BL, Banerji A, Bernstein JA, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. J Allergy Clin Immunol: In Practice. 2013; 1(5): 458-467.

Effective date: 11/01/2019
Revised date: 08/25/2017

Update record:
11/12/2019 New Marketplace for Haegarda created

CareSource Pharmacy Policy Statement
Marketplace
Hyalgan

Drug Name: Hyalgan (sodium hyaluronate)
Billing Code: J7321
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: 5 injections (5 units)

Hyalgan (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 20 mg (2 mL) once weekly for up to 5 weeks (total of 5 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 Hyalgan (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust

CareSource Pharmacy Policy Statement
Marketplace
Hyalgan

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. Hyalgan [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; May, 2014.
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. Christensen R, Bartels EM, Astrup A, Bliddal H. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and meta-analysis. Ann Rheum Dis. 2007: 66(4):433-9.
11. Carraba, M et al. 1991 Hyaluronic acid sodium salt (Hyalgan) in the treatment of patients with osteoarthritis of the knee: a controlled trial versus Orgotein, Final report. April 1991. Data on file.
12. Kotz R, Kolarz G. Intra-articular hyaluronic acid: duration of effect and results of repeated treatment cycles. Am J Ortho 1997(28):5-7.
13. Hyalgan. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 17, 2017.
14. Hyalgan. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed May 17, 2017.
15. 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.
16. 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 Hyalgan created

CareSource Pharmacy Policy Statement
Marketplace
Hymovis

Drug Name: Hymovis (sodium hyaluronate)
Billing Code: J7322
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: 2 injections (48 units)

Hymovis (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 24 mg (3 mL) once weekly for 2 weeks (total of 2 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 Hymovis (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust

CareSource Pharmacy Policy Statement
Marketplace
Hymovis

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. Hymovis [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; August, 2015. Accessed March 2016.
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. Hymovis. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 17, 2017.
11. Hymovis. 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 Hymovis created

CareSource Pharmacy Policy Statement
Marketplace
Ilumya

Drug Name: Ilumya (tildrakizumab-asmn)
Billing Code: J3590
Benefit Type: Medical
Site of Service Allowed: Outpatient/Office
Coverage Requirements: Prior Authorization Required (Non-Preferred Product)
Alternative preferred products include Cimzia, Cosentyx, Enbrel, Otezla and Siliq
Quantity Limit: 100 mg every 12 weeks after 4th week

Ilumya (tildrakizumab-asmn) 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.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:
1. Member must be 18 years of age or older with a diagnosis of moderate-to-severe chronic PsO; AND
2. Member 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 receiving Ilumya in combination with other systemic therapies (e.g., Enbrel, Humira, Cimzia, Simponi, Xeljanz, Otezla, etc.) or phototherapy; AND
6. Member's PsO involving 10% or more of the body surface area (BSA), or BSA less than 10% if there is sensitive area involvement (hands, feet, face, or genitals); AND
7. Member's Psoriasis Area and Severity Index (PASI) score ≥ 12; AND
8. Member has tried and failed to respond to treatment with at least one of the following:
   a) a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) 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) 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 12 weeks; 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:** 100 mg subcutaneously at Weeks 0, 4, and every twelve weeks thereafter, and should only be administered by a healthcare provider.

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

For **reauthorization**:
1. Member 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.).

CareSource Pharmacy Policy Statement
Marketplace
Ilumya

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

CareSource considers Ilumya (tildrakizumab-asmn) 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
- Ankylosing spondylitis
- Asthma
- Cellulitis
- Crohn's Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Infectious uveitis
- Juvenile idiopathic arthritis
- Lupus perino
- Osteoarthritis
- Psoriatic Arthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Rheumatoid arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Ulcerative Colitis
- Vogt-Koyanagi

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CareSource Pharmacy Policy Statement
Marketplace
Ilumya

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

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

CareSource Pharmacy Policy Statement
Marketplace
Immune Globulin

Drug Name:
Intravenous: Bivigam, Carimune NF, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Privigen, and Thymoglobulin
Subcutaneous: Cuvitru, Hizentra, HyQvia and Xembify
Billing Code: J1556-Bivigam; J1566-Carimune NF; J1572-Flebogamma DIF; J1569-Gammagard Liquid; J1566-Gammagard S/D; J1561-Gammaked; J1557-Gammaplex; J1561-Gamunex-C; J1568-Octagam; J1459-Privigen; J7511-Thymoglobulin; J3590-Cuvitru; J1559-Hizentra; J1575-HyQvia; J3590-Xembify
Benefit Type: Medical
Site of Service Allowed: Outpatient/Office/Home
Coverage Requirements: Prior Authorization Required
Quantity Limit: N/A

Immune Globulin (intravenous [IVIG]: Bivigam, Carimune NF, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Privigen and Thymoglobulin; subcutaneous [SCIG]: Cuvitru, Hizentra, HyQvia, and Xembify) is a product that 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.
Limitations: SCIG are only indicated for primary humoral immunodeficiency.

AUTOIMMUNE BULLOUS DISEASE

For **initial** authorization:
1. Member has contraindications to, failure of (refractory to), or significant side effects from systemic corticosteroids or immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil); AND
2. Member has dermatologic condition, as indicated by **one** or more of the following:
   a) Bullous pemphigoid;
   b) Epidermolysis bullosa acquisita;
   c) Linear IgA bullous dermatosis;
   d) Mucous membrane (cicatricial) pemphigoid;
   e) Pemphigoid gestationis;
   f) Pemphigus foliaceus;
   g) Pemphigus vulgaris.
3. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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; AND
2. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect is provided with chart notes.

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

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Immune Globulin

B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

For **initial** authorization:
1. IVIG is prescribed for prophylaxis of bacterial infections; AND
2. Member has a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization; AND
3. Member has a pretreatment serum IgG level <500 mg/dL (Copy of laboratory report with pre-treatment serum IgG level must be provided with chart notes).
4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

For **reauthorization**:
1. A reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy.

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

CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP)

For **initial** authorization:
1. Member has moderate to severe functional disability; AND
2. Electrodiagnostic studies are consistent with multifocal demyelinating abnormalities (Pre-treatment electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS] provided with chart notes); AND
3. Member has elevated CSF protein (Pre-treatment cerebrospinal fluid (CSF) analysis when available).
4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

For **reauthorization**:
1. Member has significant improvement in disability and maintenance of improvement since initiation of IVIG therapy; AND
2. In those who are clinically stable and receiving long-term treatment (i.e., more than 1 year), the dose has been tapered and/or treatment withdrawn to determine whether continued treatment is necessary; AND
3. IVIG is being used at the lowest effective dose and frequency.

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

DERMATOMYOSITIS OR POLYMYOSITIS

For **initial** authorization:
1. Diagnosis established by clinical features (e.g., proximal weakness, rash), elevated muscle enzyme levels, electrodiagnostic studies (EMG/NCS), and muscle biopsy (when available); supportive diagnostic tests include autoantibody testing and muscle imaging (e.g., MRI); AND
2. Standard first-line treatments (corticosteroids or immunosuppressants) have been tried but were unsuccessful or not tolerated; OR

3. Member is unable to receive standard first-line therapy because of a contraindication or other clinical reason.
4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

For **reauthorization**:
1. Member has significant improvement in disability and maintenance of improvement since initiation of IVIG therapy.

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

FETAL/NEONATAL ALLOIMMUNE THROMBOCYTOPENIA (F/NAIT)

For **initial** authorization:
1. Member is a newborn, and thrombocytopenia persists after transfusion of antigen-negative compatible platelet; OR
2. Member is pregnant and has diagnosis of F/NAIT with **one** or more of the following:
   a) Family history of disease;
   b) Platelet alloantibodies found on screening;
   c) Previously affected pregnancy.
3. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

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

GUILLAIN-BARRE SYNDROME (GBS)

For **initial** authorization:
1. Physical mobility is severely affected such that member requires an aid to walk; AND
2. IVIG therapy will be initiated within 2 weeks of symptom onset.
3. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

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

IDIOPATHIC THROMBOCYTOPENIC PURPURA (IMMUNE THROMBOCYTOPENIA)

For **initial** authorization:
1. Initial therapy (Member diagnosed with ITP within the past 3 months):
   a) Children (< 18 years of age):
      i) Significant bleeding symptoms (mucosal bleeding or other moderate/severe bleeding); OR
      ii) High risk for bleeding* (see Appendix A); OR
      iii) Rapid increase in platelets is required* (e.g., surgery or procedure);

   b) Adults (≥ 18 years of age):
      i) Platelet count < 30,000/mcL; OR
      ii) Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding or rapid increase in platelets is required*; AND
      iii) Corticosteroid therapy is contraindicated and IVIG will be used alone or IVIG will be used in combination with corticosteroid therapy.
2. Chronic/persistent ITP (≥ 3 months from diagnosis) or ITP unresponsive to first-line therapy (i.e., corticosteroids):
   a) Platelet count < 30,000/mcL; OR
   b) Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding* or rapid increase in platelets is required*; AND
   c) Relapse after previous response to IVIG or inadequate response/intolerance/contraindication to corticosteroid or anti-D therapy.
3. Adults with refractory ITP after splenectomy:
   a) Platelet count < 30,000/mcL; OR
   b) Significant bleeding symptoms.
4. ITP in pregnant women: authorization through delivery may be granted to pregnant women with ITP if any **one** or more of the following:
   a) Any bleeding during pregnancy;
   b) Platelet count less than 10,000/mm^3 ($10x10^9$/L) at any time during pregnancy;
   c) Platelet count between 10,000/mm^3 ($10x10^9$/L) and 30,000/mm^3 ($30x10^9$/L) in second or third trimester.
5. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

***** *The member's risk factor(s) for bleeding (see Appendix A) or reason requiring a rapid increase in platelets must be provided*.

If member meets all the requirements listed above, the medication will be approved for 1 months for initial therapy, or for 6 months for chronic/persistent ITP or for adults with refractory ITP after splenectomy.

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

KAWASAKI SYNDROME

For **initial** authorization:
1. Pediatric member with Kawasaki syndrome.
2. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

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

KIDNEY TRANSPLANT

For **initial** authorization:
1. Medication is used for prophylaxis or treatment of acute kidney rejection in conjunction with concomitant immunosuppression (e.g., cyclosporine, mycophenolate mofetil, and corticosteroids).
2. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

LAMBERT-EATON MYASTHENIC SYNDROME (LEMS)

For **initial** authorization:
1. Member has diagnosis of LEMS and steroids and other immunosuppressive treatments do not control symptoms.
2. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

For **reauthorization**:
1. Member has significant improvement in disability and maintenance of improvement since initiation of IVIG therapy.

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

MULTIFOCAL MOTOR NEUROPATHY (MMN)

For **initial** authorization:
1. Member has weakness without objective sensory loss in 2 or more nerves; AND
2. Electrodiagnostic studies (electromyography [EMG]) are consistent with motor conduction block; AND
3. Normal sensory nerve conduction studies provided in chart notes.
4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

For **reauthorization**:
1. Member has significant improvement in disability and maintenance of improvement since initiation of IVIG therapy.

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

MYASTHENIA GRAVIS

For **initial** authorization:
1. Member has Neonatal Myasthenia Gravis; OR
2. Member is adult and has worsening weakness including an increase in any of the following symptoms: diplopia, ptosis, blurred vision, difficulty speaking (dysarthria), difficulty swallowing (dysphagia), difficulty chewing, impaired respiratory status, fatigue, and limb weakness. Acute exacerbations include more severe swallowing difficulties and/or respiratory failure; OR
3. Member is adult and medication used for pre-operative management (e.g., prior to thymectomy).
4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

Note: Immune Globulin must not be used for maintenance therapy.

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

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

PARVOVIRUS B19-INDUCED PURE RED CELL APLASIA (PRCA)

For **initial** authorization:
1. Member has parvovirus B19-induced PRCA.
2. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

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

PRIMARY IMMUNODEFICIENCY

For **initial** authorization:
Member must have **one** of the following diagnoses:
1. Severe combined immunodeficiency (SCID) or congenital agammaglobulinemia (e.g., X-linked or autosomal recessive agammaglobulinemia):
   a) Diagnosis confirmed by genetic or molecular testing; OR
   b) Pretreatment IgG level < 200 mg/dL; OR
   c) Absence or very low number of T cells (CD3 T cells < 300/microliter) or the presence of maternal T cells in the circulation (SCID only);
2. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non-SCID combined immunodeficiency):
   a) Diagnosis confirmed by genetic or molecular testing (if applicable); AND
   b) History of recurrent bacterial infections (e.g., pneumonia, otitis media, sinusitis, sepsis, gastrointestinal); AND
   c) Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix B);
3. Common variable immunodeficiency (CVID):
   a) Member is 4 years of age or older; AND
   b) Other causes of immune deficiency have been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy); AND
   c) Member's pretreatment IgG level < 500 mg/dL or ≥ 2 SD below the mean for age; AND
   d) Member has a history of recurrent bacterial infections; AND
   e) Member has impaired antibody response to pneumococcal polysaccharide vaccine documented in chart notes (see Appendix B);
4. Hypogammaglobulinemia (unspecified), IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency:
   a) Member has a history of recurrent bacterial infections; AND
   b) Member has impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix B)
   c) Member has ANY of the following pre-treatment laboratory findings:
      i) Hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age;
      ii) Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels;
      iii) Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels;
      iv) IgG subclass deficiency: IgG1, IgG2, or IgG3 ≥ 2 SD below mean for age assessed on at least 2 occasions; normal IgG (total) and IgM levels, normal/low IgA levels;

   v) Specific antibody deficiency: normal IgG, IgA and IgM levels;
5. Other predominant antibody deficiency disorders must meet a), b), and c) i) in section 4. above;
6. Other combined immunodeficiency must meet criteria in section 2. above.
7. **Dosage allowed:** Please see dosage and administration information in individual drug package insert. *Note:* Gammagard Liquid, Gamunex-C, and Gammaked may be administered intravenously or subcutaneously for primary immunodeficiency.

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

For **reauthorization**:
1. A reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy; AND
2. IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication); OR
3. The prescriber will re-evaluate the dose of IVIG and consider a dose adjustment (when appropriate).

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

PROPHYLAXIS OF BACTERIAL INFECTIONS IN BMT/HSCT RECIPIENTS

For **initial** authorization:
1. Member is BMT/HSCT recipient; AND
2. IVIG is prescribed for prophylaxis of bacterial infections; AND
3. Either of the following:
   a) IVIG is requested within the first 100 days post-transplant; OR
   b) Member has a pretreatment serum IgG < 400 mg/dL.
4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

For **reauthorization**:
1. Reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy and documented in chart notes.

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

PROPHYLAXIS OF BACTERIAL INFECTIONS IN HIV-INFECTED PEDIATRIC PATIENTS

For **initial** authorization:
1. Member with HIV infection and is 18 years of age or younger; AND
2. IVIG is prescribed for **primary** prophylaxis of bacterial infections and pretreatment serum IgG < 400 mg/dL; OR
3. IVIG is prescribed for **secondary** prophylaxis of bacterial infections with ALL of the following:
   a) History of recurrent bacterial infections (> 2 serious bacterial infections in a 1-year period);
   b) Member is not able to take combination antiretroviral therapy;
   c) Antibiotic prophylaxis was tried but was not effective (e.g., trimethoprim-sulfamethoxazole).

4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

For **reauthorization**:
1. Reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy and documented in chart notes.

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

STIFF-PERSON SYNDROME

For **initial** authorization:
1. Medication is used for treatment of stiff-person syndrome in members who have experienced an inadequate response or intolerance, or have a contraindication to first-line therapy such as a benzodiazepine (e.g., diazepam) and/or baclofen.
2. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

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

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

CareSource considers Immune Globulin (intravenous [IVIG]: Bivigam, Carimune NF, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Privigen, Thymoglobulin; subcutaneous [SCIG]: Cuvitru, Hizentra, HyQvia) 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 hemophilia	Myocarditis, acute
Adrenoleukodystrophy	Neonatal sepsis, prevention
Alzheimer's disease	Neonatal sepsis, treatment
Amyotrophic lateral sclerosis (ALS)	Ocular myasthenia
Antiphospholipid antibody syndrome (APS) in pregnancy	Paraneoplastic cerebellar degeneration, sensory neuropathy, or encephalopathy
Asthma, non-steroid dependent	Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
Atopic dermatitis	POEMS syndrome
Autism spectrum disorders	Postinfectious cerebellar ataxia
Autoimmune liver disease	Postoperative sepsis
Autoimmune neutropenia	Pseudomembranous colitis
Campylobacter species-induced enteritis	Respiratory syncytial virus (RSV) lower respiratory tract infection
Cerebral infarctions with antiphospholipid antibodies	Rheumatic fever, acute
Chronic fatigue syndrome	Sjogren's syndrome

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Demyelinative brain stem encephalitis	Spontaneous recurrent abortions, prevention
Demyelinating neuropathy associated with monoclonal IgM	Systemic lupus erythematosus
Dilated cardiomyopathy	Urticaria, chronic
HIV infection or prophylaxis	Vasculitides and antineutrophil antibody syndromes
HTLV-1-associated myelopathy	Routine prophylaxis of Measles, Varicella, and Rubella
Idiopathic dysautonomia, acute	Treatment of Measles, Varicella, and Rubella
Inclusion body myositis	
Isolated IgA deficiency	
Isolated IgG4 deficiency	
Lumbosacral or brachial plexitis	

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Effective date: 11/01/2019
Revised date: 08/21/2019

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