



Administrative Policy Statement GEORGIA MEDICAID

Policy Name		Policy Number	Date Effective
Site of Care for Drug Administration		PAD-0019-GA-MCD	07/01/2020
Policy Type			
Medical	ADMINISTRATIVE	Pharmacy	Reimbursement

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Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

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A. SUBJECT

This policy outlines required criteria for administration of drugs at the hospital outpatient setting as the site of service and directs members to the most cost-effective site of care. It also outlines medications to which this policy applies.

B. BACKGROUND

The CareSource Pharmacy Policy Statement is a guideline for determining site of care coverage for selected drugs. It is used as a tool to be interpreted in conjunction with the member's specific benefit plan. The intent of CareSource Site of Care for Drug Administration policy is to outline the requirements for coverage for the outpatient hospital drug administration.

C. DEFINITIONS

- Site of Care: Choice for physical location of infusion administration. Sites of Care include hospital inpatient, hospital outpatient, provider's office, ambulatory infusion center, or home-based setting.

D. POLICY

This policy does not apply to the first administration of a drug. The first dose can be administered at any facility of the physician's choice. All subsequent doses will be subject to the CareSource Site of Care for Drug Administration policy which requires the use of a non-hospital outpatient facility or home care setting.

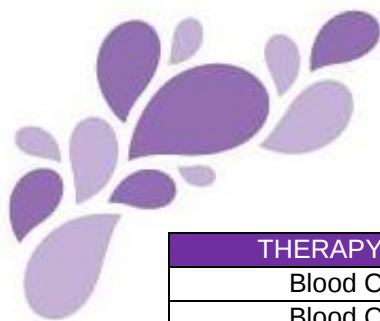
Note: Therapy that consists of a single administration of a drug is considered the first administration.

I. CareSource considers outpatient hospital facility-based intravenous medication infusion necessary if member meets one of the following:

- A. Member is initiating therapy for the first time or therapy reinitiated after more than 6 months;
- B. Member has documentation of previously severe or potentially life-threatening adverse event (e.g., anaphylaxis, seizures, renal failure, etc.) during or following infusion of the prescribed medication, and the adverse event cannot be managed through pre-medication in the home or office setting;
- C. Member is medically unstable for administration of the therapy due to one of the following:
 1. history of cardiopulmonary conditions
 2. difficulty establishing and maintaining vascular access
 3. physical or cognitive impairments that can cause an unnecessary health risk
 4. unstable renal function;
- D. Medication requested is not available for administration at one of the following:
 1. non-hospital outpatient facility
 2. physician's office
 3. home-based setting
 4. ambulatory infusion center;

II. CareSource requires subsequent doses of the following medications to be administered in a non-hospital outpatient facility, provider's office, ambulatory infusion center or home setting:

THERAPY DESCRIPTION	CODE	BRAND NAME
Alpha-1 Deficiency	J0256	Aralast NP, Prolastin, Zemaira
Alpha-1 Deficiency	J0257	Glassia
Blood Cell Deficiency	J0881	Aranesp
Blood Cell Deficiency	J0885	Epogen, Procrit



THERAPY DESCRIPTION	CODE	BRAND NAME
Blood Cell Deficiency	J1447	Granix
Blood Cell Deficiency	J2820	Leukine
Blood Cell Deficiency	J2562	Mozobil
Blood Cell Deficiency	J2505	Neulasta
Blood Cell Deficiency	J1442	Neupogen
Enzyme Deficiencies	J1931	Aldurazyme
Enzyme Deficiencies	J1786	Cerezyme
Endocrine Disorders	J0584	Crysvita
Enzyme Deficiencies	J1743	Elaprase
Enzyme Deficiencies	J3060	Elelyso
Enzyme Deficiencies	J0180	Fabrazyme
Enzyme Deficiencies	J0221	Lumizyme
Enzyme Deficiencies	J3397	Mepsevii
Enzyme Deficiencies	J1458	Naglazyme
Enzyme Deficiencies	J1322	Vimizim
Enzyme Deficiencies	J3385	VPRIV
Growth Deficiency	J1930	Somatuline Depot
Hemophila/Bleeding Disorders	J7192	Advate
Hemophila/Bleeding Disorders	J7207	Adynovate
Hemophila/Bleeding Disorders	J7210	Afstyla
Hemophila/Bleeding Disorders	J7186	Alphanate
Hemophila/Bleeding Disorders	J7193	Alphanine
Hemophila/Bleeding Disorders	J7201	Alprolix
Hemophila/Bleeding Disorders	J7194	Bebulin
Hemophila/Bleeding Disorders	J7195	Benefix
Hemophila/Bleeding Disorders	J2724	Ceprotrin
Hemophila/Bleeding Disorders	J7180	Corifact
Hemophila/Bleeding Disorders	J2597	DDAVP
Hemophila/Bleeding Disorders	J7205	Eloctate
Hemophila/Bleeding Disorders	J7198	Feiba NF
Hemophila/Bleeding Disorders	J7170	Hemlibra
Hemophila/Bleeding Disorders	J7192	Helixate FS
Hemophila/Bleeding Disorders	J7190	Hemofil M
Hemophila/Bleeding Disorders	J7187	Humate-P
Hemophila/Bleeding Disorders	J7202	Idelvion
Hemophila/Bleeding Disorders	J7198	Ixinity
Hemophila/Bleeding Disorders	J7199	Jivi
Hemophila/Bleeding Disorders	J7190	Koate-DVI
Hemophila/Bleeding Disorders	J7192	Kogenate
Hemophila/Bleeding Disorders	J7193	Mononine
Hemophila/Bleeding Disorders	J7182	Novoeight
Hemophila/Bleeding Disorders	J7189	Novoseven
Hemophila/Bleeding Disorders	J7209	Nuwiq
Hemophila/Bleeding Disorders	J7194	Profilinine
Hemophila/Bleeding Disorders	J7192	Recombinate
Hemophila/Bleeding Disorders	J7178	RiaSTAP
Hemophila/Bleeding Disorders	J7200	Rixubis



THERAPY DESCRIPTION	CODE	BRAND NAME
Hemophila/Bleeding Disorders	J7181	Tretten
Hemophila/Bleeding Disorders	J7183	Wilate
Hemophila/Bleeding Disorders	J7185	Xyntha
Hereditary Angioedema	J0597	Berinert
Hereditary Angioedema	J0598	Cinryze
Hereditary Angioedema	J1744	Firazyr
Hereditary Angioedema	J0599	Haegarda
Hereditary Angioedema	J1290	Kalbitor
Hereditary Angioedema	J0596	Ruconest
HIV	J1746	Trogarzo
Immune Deficiency	J1566	Carimune NF
Immune Deficiency	J1555	Cuvitru
Immune Deficiency	J1569	Gammagard Liquid
Immune Deficiency	J1666	Gammagard S-D
Immune Deficiency	J1561	Gammaked
Immune Deficiency	J1557	Gammaplex
Immune Deficiency	J1561	Gamunex-C
Immune Deficiency	J1559	Hizentra
Immune Deficiency	J1575	HyQvia
Immune Deficiency	J1568	Octagam
Immune Deficiency	J1459	Privigen
Inflammatory Conditions	J3262	Actemra
Inflammatory Conditions	J0490	Benlysta
Inflammatory Conditions	J0717	Cimzia
Inflammatory Conditions	J3380	Entyvio
Inflammatory Conditions	J0638	Ilaris
Inflammatory Conditions	Q5103	Inflectra
Inflammatory Conditions	J0129	Orencia
Inflammatory Conditions	J1745	Remicade
Inflammatory Conditions	Q5104	Renflexis
Inflammatory Conditions	J1602	Simponi Aria
Inflammatory Conditions	J3358	Stelara IV
Miscellaneous Diseases	J0364	Apokyn
Miscellaneous Diseases	J3590	Myalept
Miscellaneous Diseases	J1300	Soliris
Miscellaneous Diseases	J1628	Tremfya
Miscellaneous Diseases	J3590	Ultomiris
Multiple Sclerosis	J0202	Lemtrada
Multiple Sclerosis	J2350	Ocrevus
Multiple Sclerosis	J2323	Tysabri
Pulmonary Hypertension	J1325	Flolan
Pulmonary Hypertension	J3285	Remodulin
Pulmonary Hypertension	J7686	Tyvaso
Pulmonary Hypertension	J1325	Veletri
Pulmonary Hypertension	Q4074	Ventavis
Transplant	J0485	Nulojix



E. CONDITIONS OF COVERAGE

As above.

F. RELATED POLICIES/RULES

Selected individual drug policies can be found at:

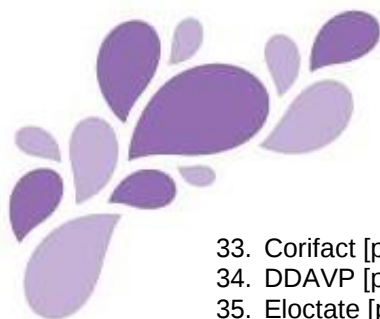
<https://www.caresource.com/ga/providers/tools-resources/health-partner-policies/pharmacy-policies/medicaid/>

G. REVIEW/REVISION HISTORY

	DATES	ACTION
Date Issued	08/21/2019	Initial release
Date Revised		
Date Effective	07/01/2020	
Date Archived	09/01/2020	

H. REFERENCES

1. Aralast NP [prescribing information]. Westlake Village, CA: Baxalta US Inc.; September 2015.
2. Glassia [prescribing information]. Lexington, MA: Baxalta US Inc.; June 2017.
3. Prolastin-C [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2018.
4. Zemaira [prescribing information]. Kankakee, IL: CSL Behring LLC; September 2015.
5. Aranesp [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; January 2019.
6. Epogen [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; July 2018.
7. Procrit [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; June 2011.
8. Granix [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
9. Leukine [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; February 2017.
10. Mozobil [prescribing information]. Cambridge, MA: Genzyme Corporation; May 2019.
11. Neulasta [prescribing information]. Thousand Oaks, CA: Amgen Inc.; April 2019.
12. Neupogen [prescribing information]. Thousand Oaks, CA: Amgen; June 2018.
13. Aldurazyme [prescribing information]. Cambridge, MA: Genzyme Corporation; April 2013.
14. Cerezyme [prescribing information]. Cambridge, MA: Genzyme Corporation; April, 2018.
15. Crysvita [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; April, 2018.
16. Elaprase [prescribing information]. Lexington, MA: Shire Human Genetic Therapies, Inc.; November 2018.
17. Elelyso [prescribing information]. New York, NY: Pfizer Inc.; December 2016.
18. Fabrazyme [prescribing information]. Cambridge, MA: Genzyme Corporation; December 2018.
19. Lumizyme [prescribing information]. Cambridge, MA: Genzyme Corporation; May 2019.
20. Mepsevii [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; November, 2017.
21. Naglazyme [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; March 2013.
22. Vimizim [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; February 2014.
23. VPRIV [prescribing information]. Lexington, MA: Shire Human Genetic Therapies, Inc.; July 2019.
24. Somatuline Depot [prescribing information]. Basking Ridge, NJ: Ipsen Pharma Biotech; June 2019.
25. Advate [prescribing information]. Westlake Village, CA: Baxalta US Inc; Nov 2016.
26. Adynovate [prescribing information]. Westlake Village, CA: Baxalta US Inc; March 2017.
27. Afstylia [prescribing information]. Kankakee, IL: CSL Behring LLC; Sept 2017.
28. Alphanate [prescribing information]. Los Angeles, CA: Grifols Biologicals Inc.; June 2014.
29. Alphanine SD [prescribing information]. Los Angeles, CA: Grifols Biologicals Inc.; March 2017.
30. Alprolix [prescribing information]. Cambridge, MA: Biogen Inc.; November 2017.
31. Bebulin VH [prescribing information]. Westlake Village, CA: Baxalta US Inc; July 2012.
32. Benefix [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; June 2017.



33. Corifact [prescribing information]. Kankakee, IL: CSL Behring LLC; Sept 2017.
34. DDAVP [prescribing information]. Bridgewater, NJ: Sanofi-Aventis U.S.LLC.; July 2007.
35. Eloctate [prescribing information]. Waltham, MA: Bioverativ Therapeutics Inc.; Dec 2017.
36. Feiba [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation.; Nov 2013.
37. Feiba NF [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation.; Feb 2011.
38. Feiba VH [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation.; Apr 2005
39. Helixate FS [prescribing information]. Kankakee, IL: CSL Behring LLC.; May 2014.
40. Hemlibra [prescribing information]. South San Francisco, CA: Genentech, Inc.; Nov 2017
41. Hemofil M [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation.; April 2012.
42. Humate-P [prescribing information]. Kankakee, IL: CSL Behring LLC.; Aug 2013.
43. Idelvion [prescribing information]. Kankakee, IL: CSL Behring LLC.; March 2016.
44. Ixinity [prescribing information]. Berwyn, PA: Aptevo BioTherapeutics LLC; April 2018.
45. Kcentra [prescribing information]. Kankakee, IL: CSL Behring LLC.; Dec 2013.
46. Koate-DVI [prescribing information]. Los Angeles, CA: Grifols Biologicals Inc.; Aug 2012.
47. Kogenate FS [prescribing information]. Tarrytown, NY: Bayer Healthcare; May 2014.
48. Kovaltry [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; March 2016.
49. Monoclate-P [prescribing information] Kankakee, IL: ZLB Behring LLC.; Aug 2004
50. Mononine [prescribing information]. Kankakee, IL: CSL Behring LLC.; Feb 2013.
51. Novoeight [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; June 2018.
52. Novoseven RT [prescribing information]. Bagsvaerd, Denmark: Novo Nordisk A/S.; May 2014.
53. NuwiQ [prescribing information]. Hoboken, NJ: Octapharma USA Inc.; Sept 2015.
54. Obizur [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation.; Oct 2014
55. Profilnine [prescribing information]. Los Angeles, CA: Grifols Biologicals Inc.; Aug 2010.
56. Rebinyn [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; May 2017.
57. Recombinate [prescribing information] Westlake Village, CA: Baxter Healthcare Corporation.; Dec 2010.
58. RiaSTAP [prescribing information] Kankakee, IL: CSL Behring LLC.; Dec 2011.
59. Rixubis [prescribing information]. Westlake Village, CA: Baxalta US Inc.; Sept 2014.
60. Tretten [prescribing information]. Bagsvaerd, Denmark: Novo Nordisk A/S.; Apr 2014.
61. VonVendi [prescribing information]. Westlake Village, CA: Baxalta US Inc.; Dec 2015.
62. Wilate [prescribing information]. Hoboken, NJ: Octapharma USA Inc.; Aug 2010.
63. Xyntha [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; Oct 2014.
64. Jivi [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; August 2018.
65. Berinert [prescribing information]. Kankakee, IL: CSL Behring LLC; September, 2016.
66. Cinryze [prescribing information]. Exton, PA; ViroPharma Biologics, Inc.; June 2018.
67. Firazyr [prescribing information]. Lexington, MA; Shire Orphan Therapies, Inc.; August 2011.
68. Haegarda [prescribing information]. Kankakee, IL: CSL Behring LLC; June 2017.
69. Kalbitor [prescribing information]. Burlington, MA; Dyax Corp.; September 2014.
70. Ruconest [prescribing information]. Raleigh, NC; Salix Pharmaceuticals, Inc.; July 2014.
71. Trogarzo [prescribing information]. Irvine, CA: TaiMed Biologics USA Corp.; March 2018.
72. Carimune NF [prescribing information]. Kankakee, IL: CSL Behring LLC; September 2013.
73. Cuvitru [prescribing information]. Westlake Village, CA: Baxalta US Inc.; September 2016.
74. Gammagard Liquid [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation; April 2014.
75. Gammagard S/D [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation; April 2014.
76. Gammaked [prescribing information]. Fort Lee, NJ: Kedrion Biopharma, Inc.; September 2013.
77. Gammaplex [prescribing information]. Hertfordshire, United Kingdom: Bio Products Laboratory; July 2015.
78. Gamunex-C [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics Inc.; July 2014.
79. Octagam 10% [prescribing information]. Hoboken, NJ: Octapharma USA, Inc.; April 2015.



80. Octagam 5% [prescribing information]. Hoboken, NJ: Octapharma USA, Inc.; October 2014.
81. Privigen [prescribing information]. Kankakee, IL: CSL Behring LLC; November 2013.
82. Hizentra [prescribing information]. Kankakee, IL: CSL Behring LLC; October 2016.
83. HyQvia [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation; September 2016.
84. Actemra [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2018.
85. Benlysta [prescribing information]. Rockville, MD: Human Genome Sciences, Inc.; March 2011.
86. Cimzia [prescribing information]. Smyrna, GA: UCB, Inc.; May 2018.
87. Entyvio [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2014.
88. Ilaris [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December, 2016.
89. Inflectra [prescribing information]. New York, NY: Pfizer Inc.; June 2019.
90. Orencia [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2017.
91. Remicade [prescribing information]. Horsham, PA; Janssen Biotech, Inc.; January 2015.
92. Renflexis [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2019.
93. Simponi Aria [prescribing information]. Horsham, PA; Janssen Biotech, Inc.; October 2017.
94. Stelara [prescribing information]. Horsham, PA: Janssen Biotech Inc.; October 2017.
95. Apokyn [prescribing information]. Louisville, KY: US WorldMeds, LLC; May 2019.
96. Myalept [prescribing information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; September 2015.
97. Soliris [prescribing information]. New Haven, CT: Alexion Pharmaceuticals Inc.; January 2017.
98. Tremfya [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
99. Ultomiris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; December 2018.
100. Lemtrada [prescribing information]. Cambridge, MA: Genzyme, Inc.; June 2016.
101. Ocrevus [prescribing information]. San Francisco, CA; Genentech, Inc.; March 2017.
102. Tysabri [prescribing information]. Cambridge, MA: Biogen, Inc.; December 2016.
103. Flolan [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2018.
104. Remodulin [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp; July 2018.
105. Tyvaso [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp.; October 2017.
106. Veletri [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; December 2018.
107. Ventavis [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; October 2017.
108. Nulozif [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; April 2018.