MASSACHUSETTS

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Medicare Medical Policy

Medicare Advantage Part B Step Therapy

Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Policy Number: 020

Related Policies

- Quality Care Cancer Program (Medical Oncology), #099
- Supportive Care Treatments for Patients with Cancer, #105

This policy will only manage non-oncology indications for drugs with both oncology and non-oncology indications. For the management of oncology or supportive care indications, please see related policies above that are managed by Carelon (Medical Policy #099 and #105).

Note: All preservice authorization requests may be submitted to BCBSMA Clinical Pharmacy Operations by completing the preservice authorization form on the last page of this document. Prescribers may also call BCBSMA Pharmacy Operations department at (800) 366-7778 to request a preservice authorization verbally.

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NCD/LCD/Article

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

National Coverage Determinations (NCDs)
Local Coverage Determinations (LCDs) for National Government Services, Inc.

Note: To review the specific NCD/LCD/Article, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

For specific CMS guidance, please click on the medication hyperlink below.

Please refer to the chart below for the formulary status of the drugs/devices affected by this policy.

Drug Class: Granulocyte Colony Stimulants (filgrastim): Zarxio; Neupogen, Nivestym, Releuko	
STEP 1	
• Step 1 Drug(s): Zarxio	Covered
STEP 2	
• Step 2 Drug(s): Neupogen, Nivestym, Releuko	Prior Use of Step 1 Required

Drug Class: Erythropoiesis Stimulants: Retacrit; Aranesp, Epogen, Mircera, Procrit	
STEP 1	
• Step 1 Drug(s): Retacrit	Covered
STEP 2	
• Step 2 Drug(s): Aranesp, Epogen, Mircera, Procrit	Prior Use of Step 1 Required

Device Class: Hyaluronate and Derivatives: Hyalgan, Hymovis, Synvisc; Durolane, Euflexxa, Gel-One, Gelsyn-3, Genvisc, Monovisc, Orthovisc, Supartz Fx, Triluron, Trivisc, Visco-3	
STEP 1	
• Step 1 Drug(s): Euflexxa, Synvisc	Covered
STEP 2	
• Step 2 Drug(s): Durolane, Gel-One, Gelsyn-3, Genvisc, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz Fx, Triluron, Trivisc, Visco-3	Prior Use of Step 1 Required

Drug Class: Tumor Necrosis Factor (TNF) Blocking Agents: Inflectra; Remicade, Renflexis, Avsola	
STEP 1	
• Step 1 Drug(s): Inflectra, Avsola	Covered
STEP 2	
• Step 2 Drug(s): Infliximab, Remicade, Renflexis	Prior Use of Step 1 Required

Drug Class: Vascular Endothelial Growth Factor (VEGF) Inhibitors: Avastin; Beovu, Eylea, Eylea HD, Lucentis, Macugen	
STEP 1	
• Step 1 Drug(s): Avastin	Covered
STEP 2	

• Step 2 Drug(s): Beovu, Byooviz, Cimerli, Eylea, Eylea HD, Lucentis, Macugen, Susvimo, Vabysmo	Prior Use of Step 1 Required

Drug Class: Bisphosphonates and Bone Modifying Agent: Bisphosphonates, Prolia	
STEP 1	
• Step 1 Drug(s): Bisphosphonates	Covered
STEP 2	
• Step 2 Drug(s): Prolia (osteoporosis only)	Prior Use of Step 1 Required

Drug Class: Anti-CD20 Monoclonal Antibody: Ruxience, Truxima; Rituxan, Riabni	
STEP 1	
• Step 1 Drug(s): Ruxience, Truxima	Covered
STEP 2	
• Step 2 Drug(s): Rituxan, Riabni	Prior Use of Step 1 Required

Medical necessity criteria will follow CMS NCD/LCD/Article guidance. In addition, we may cover the following drug/device classes listed in the chart above for new starts* in the following stepped approach:

*New starts are defined as no previous claim or prescriber documented use for the requested Step 2 drug/device within the past 365 days.

Step 1: Step 1 drugs/devices will be covered without a preservice authorization.

Step 2: Step 2 drugs/devices may be covered when all of the following criteria are met:
- The drug/device must be used for a medically accepted indication that is supported by the Food and Drug Administration (FDA) labeling of the drug and/or medical references approved by Medicare.
- There must be evidence of a BCBSMA claim or prescriber documented use of a Step 1 drug/device within the previous 365 days.

Additional clinical information demonstrating medical necessity of the desired drug/device must be submitted by the requesting prescriber for review.

We do not cover drugs/devices listed in the above chart unless the above step therapy criteria are met.

Medicare Advantage HMO and PPO Blue Members

In which settings is preservice authorization required?

Step therapy will be required when the medications are administered using a member's **medical benefit** in these settings:
- A clinician's or physician's office
- A home health care provider
- A home infusion therapy provider
- Outpatient hospital and dialysis settings
- Surgical day care.

Note: This change does not affect these medications in inpatient, urgent care centers, and emergency department settings.

Prescribers may send relevant clinical information to:
Blue Cross Blue Shield of Massachusetts, Pharmacy Operations Department
25 Technology Place, Hingham, MA 02043
Tel: 1-800-366-7778; Fax: 1-866-463-7700

Applicable HCPCS Codes-

HCPCS Codes	Description
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram
J1442	Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram
Q5105	Injection, epoetin alfa, biosimilar, (retacrit) (for esrd on dialysis), 100 units
Q5106	Injection, epoetin alfa, biosimilar, (retacrit) (for non-esrd use), 1000 units
J0881	Injection, darbepoetin alfa, 1 microgram (non-esrd use)
J0882	Injection, darbepoetin alfa, 1 microgram (for esrd on dialysis)
J0885	Injection, epoetin alfa, (for non-esrd use), 1000 units
Q4081	Injection, epoetin alfa, 100 units (for esrd on dialysis)
J0887	Injection, epoetin beta, 1 microgram, (for esrd on dialysis)
J0888	Injection, epoetin beta, 1 microgram, (for non esrd use)
J7321	Hyaluronan or derivative, hyalgan, supartz or visco-3, for intra-articular injection, per dose
J7322	Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg
J7325	Hyaluronan or derivative, synvisc or synvisc-one, for intra-articular injection, 1 mg
J7327	Hyaluronan or derivative, monovisc, for intra-articular injection, per dose
J7324	Hyaluronan or derivative, orthovisc, for intra-articular injection, per dose
J7323	Hyaluronan or derivative, euflexxa, for intra-articular injection, per dose
J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg
J7326	Hyaluronan or derivative, gel-one, for intra-articular injection, per dose
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg
J7320	Hyaluronan or derivative, genvisc 850, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg
J7329	Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
J9035	Injection, bevacizumab, 10 mg
C9257	Injection, bevacizumab, 0.25 mg
J0179	Injection, brolucizumab-dbll, 1 mg
J0177	Injection, aflibercept, (eylea hd) 1mg
J0178	Injection, aflibercept, (eylea) 1 mg
J2778	Injection, ranibizumab, 0.1 mg
J2503	Injection, pegaptanib sodium, 0.3 mg
J0897	Injection, denosumab, 1 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg
J9312	Injection, rituximab, 10 mg
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg
J2279	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2777	Injection, faricimab-svoa (vabysmo), 0.1 mg
Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg

Policy History

Date	Action
5/1/2024	Eylea HD (aflibercept) added to the Drug Class “Vascular Endothelial Growth Factor (VEGF) Inhibitors” as a second line agent.
12/21/2023	Policy updated to add Vabysmo and Susvimo as step 2 medications to Avastin; for drug class Anti-CD20 Monoclonal Antibodies, Truxima will move from a step 2 medication to a step 1 medication and Riabni will move from a step 1 medication to a

	step 2 medication; for drug class Tumor Necrosis Factor (TNF) Blocking Agents, infliximab (non-branded version of Remicade) will be added as a step 2 medication. Prior authorization will be required for members new to therapy; existing users within the past 365 days will be grandfathered. Effective 1/1/2024.
6/11/23	Policy updated to include new LCD for Intraarticular Knee Injections of Hyaluronan (L39529). Effective 6/11/23.
5/1/23	Policy updated to include J-code for Cimerli
2/1/23	Policy updated to add Cimerli as step 2 medication. Policy reviewed and approved by P&T 11/28/22. Effective 2/1/23.
10/1/22	Policy updated to add Byooviz as step 2 medication. Policy reviewed and approved by P&T 7/27/22. Effective 10/1/2022.
7/1/2022	Policy updated to move Riabni as step 1 medication and Truxima as a step 2 medication. Policy reviewed and approved by P&T 5/25/22. Effective 7/1/2022.
4/1/2022	Policy updated to move Avsola as step 1 medication. Policy reviewed and approved by P&T 3/23/22. Effective 4/1/2022.
1/1/2022	Policy updated to move Euflexxa as step 1 medication and Hyalgan and Hymovis as step 2 medication. Policy reviewed and approved by P&T 11/17/2021. Effective 1/1/2022.
12/1/2021	Policy updated to remove Mvasi and Zirabev as step 1 medication. Effective 12/1/2021.
8/1/2021	Policy updated to include Riabni for non-oncology indications only. Policy reviewed and approved by P&T 3/24/2021. Effective 8/1/2021.
7/1/2021	Policy updated to move Granix and Granulocyte Colony Stimulants (pegfilgrastim) to Carelon MP#105; Move Anti-HER2 Monoclonal Antibody to Carelon MP#99. Effective 7/1/2021.
1/1/2021	Policy updated to include the following drugs: Avsola, Bisphosphonates, Prolia, Ruxience, Truxima, Rituxan, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera, Herceptin. Policy reviewed and approved by P&T 11/17/2020. Effective 1/1/2021.
9/1/2020	Policy updated to include the following drugs: Beovu, Mvasi, Triluron, Ziextenzo, Zirabev. Policy reviewed and approved by P&T 5/19/2020. Effective 9/1/2020.
1/1/2020	New policy. Policy reviewed and approved by P&T 9/17/2019. Effective 1/1/2020.

References

1. Zarxio ™ [package insert]. Princeton, NJ: Sandoz Inc.; August 2019.
2. Neupogen™ [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2018.
3. Nivestym™ [package insert]. Lake Forest, IL: Hospira, Inc., a subsidiary of Pfizer Inc.; July 2018.
4. Retacrit™ [package insert]. Lake Forest, IL: Hospira, Inc., a subsidiary of Pfizer Inc.; January 2019.
5. Aranesp™ [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2019.
6. Epogen™ [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2018.
7. Mircera™ [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; June 2018.
8. Procrit™ [package insert]. Horsham, PA: Janssen Products, LP; July 2018.
9. Hyalgan™ [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; May 2014.
10. Hymovis™ [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; October 2015.
11. Synvisc™ [package insert]. Cambridge, MA: Genzyme Corporation; February 2009.
12. Durolane™ [package insert]. Durham, NC: Bioventus LLC; March 2018.
13. Euflexxa™ [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; July 2016.
14. Gel-One™ [package insert]. Warsaw, IN: Zimmer Inc.; September 2016.
15. Gelsyn-3™ [package insert]. Durham, NC: Bioventus LLC; August 2016.
16. Genvisc™ [package insert]. Doylestown, PA: OrthogenRx, Inc. September 2015.
17. Monovisc™ [package insert]. Beford, MA: Anika Therapeutics, Inc. December 2007.
18. Orthovisc™ [package insert]. Woburn, MA: Anika Therapeutics, Inc. February 2004.
19. Supartz Fx™ [package insert]. Durham, NC: Bioventus LLC; January 2001.
20. Triluron™ [package insert]. Florham Park, NJ: Fidia Pharma; July 2019.
21. Trivisc™ [package insert]. Doylestown, PA: OrthogenRx, Inc. November 2017.
22. Visco-3™ [package insert]. Durham, NC: Bioventus LLC; December 2015.
23. Infliximab [package insert]. Horsham, PA: Jannsen Biotech, Inc,; October 2021.
24. Inflectra™ [package insert]. New York, NY: Pfizer Labs, Division of Pfizer Inc; June 2019.

25. Remicade™ [package insert]. Horsham, PA: Janssen Biotech, Inc. October 2017.
26. Renflexis™ [package insert]. Whitehouse Station, NJ: Merck &Co., Inc. June 2019.
27. Avsola™ [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2019.
28. Avastin™ [package insert]. South San Francisco, CA: Genentech, Inc.; June 2019.
29. Beovu® [package insert]. East Hanover, NJ. Novartis Pharmaceuticals; January 2020.
30. Eylea™ [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2019.
31. Eylea™ HD [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
32. Lucentis™ [package insert]. South San Francisco, CA: Genentech, Inc.; March 2018.
33. Macugen™ [package insert]. Bridgewater, NJ: Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC; July 2016.
34. Prolia® [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2019.
35. Ruxience® [package insert]. New York, NY: Pfizer Labs, Division of Pfizer Inc; May 2020.
36. Truxima® [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2020.
37. Rituxan® [package insert]. South San Francisco, CA: Biogen and Genentech, Inc.; September 2019.
38. Riabni™ [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2020.
39. Byooviz™ [package insert]. Cambridge, MA: Biogen Inc. and Incheon, Korea: Samsung Bioepis Co. Ltd.; April 2022.
40. Cimerli™ [package insert]. Redwood City, California: Coherus BioSciences, Inc.; October 2022.
41. Vabysmo™ [package insert]. South San Fransisco, CA: Genentech, Inc.; January 2023.
42. Susvimo™ [package insert]. South San Fransisco, CA: Genentech, Inc.; April 2022.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://provider.bluecrossma.com/eforms/medication-prior-auth?secure=false