

Policy: MBP 300.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Medical Benefit Drug Optimization Program

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
CHIP			

I. Policy:

Medical Benefit Drug Optimization Program

II. Purpose/Objective:

To provide a policy of coverage regarding certain complex, rare disease, and specialty drugs, which are required to be obtained from and billed by a Specialty Pharmacy and are not eligible for direct reimbursement to a provider or facility.

This policy applies to these medications:

1. AbobotulinumtoxinA (Dysport)
2. Ado-Trastuzumab Emtansine (Kadcyla)
3. Aripiprazole (Abilify Maintena, Abilify Asimtufii)
4. Aripiprazole lauroxil (Aristada Initio, Aristada)
5. Asparaginase (Erwinia [Recombinant]) (Rylaze)
6. Atezolizumab (Tecentriq)
7. Avelumab (Bavencio)
8. Belatacept (Nulojix)
9. Belinostat (Beleodaq)
10. Brentuximab Vedotin (Adcetris)
11. Bortezomib
12. Carfilzomib (Kymprolis)
13. Cemiplimab (Libtayo)
14. Collagenase (Xiaflex)
15. Daunorubicin and Cytarabine (Liposomal) (Vyxeos)
16. Daratumumab (Darzalex)
17. Daratumumab and Hyaluronidase (Darzalex Faspro)
18. DaxibotulinumtoxinA (Daxxify)
19. Dostarlimab (Jemperli)
20. Durvalumab (Imfinzi)
21. Eribulin (Halaven)
22. Enfortumab Vedotin (Padcev)
23. Fam-Trastuzumab Deruxtecan (Enhertu)
24. Fluphenazine deconate
25. Haloperidol deconate
26. IncobotulinumtoxinA (Xeomin)
27. Inotuzumab Ozogamicin (Besponsa)
28. Ipilimumab (Yervoy)
29. Mogamulizumab (Poteligeo)
30. Nivolumab (Opdivo)
31. Nivolumab and hyaluronidase-nvhy (Opdivo Qvantig)
32. Obinutuzumab (Gazyva)
33. Octreotide (Sandostatin LAR)
34. Olanzapine (Zyprexa Relprevv)
35. OnabotulinumtoxinA (Botox)
36. Paliperidone (Invega Sustenna, Invega Hafyera, Invega Trinza)
37. Panitumumab (Vectibix)
38. Pegloticase (Krystexxa)
39. Pembrolizumab (Keytruda)
40. Polatuzumab Vedotin (Polivy)
41. Ramucirumab (Cyramza)
42. Relatlimab and nivolumab (Opdualag)
43. Retifanlimab (Zynyz)
44. RimabotulinumtoxinB (Myobloc)
45. Risperidone (Perseris, Risperdal Consta, Rykindo, Uzedly)
46. Rituximab (Rituxan)
47. Rituximab and Hyaluronidase (Rituxan Hycela)
48. Romidepsin (Istodax)
49. Romiplostim (Nplate)
50. Tislelizumab (Tevimbra)
51. Toripalimab (Loqtorzi)
52. Trastuzumab (Herceptin)
53. Tremelimumab (Imjudo)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Health Plan – Shall refer to Geisinger Health Plan and Geisinger Indemnity Insurance Company collectively.
6. Revised – the date of every revision to the policy, including typographical and grammatical changes.
7. Reviewed – the date documenting the annual review if the policy has no revisions necessary.
8. Specialty Medication – high-cost prescriptions used to treat and manage complex and chronic conditions. Specialty medications sometimes require special handling and administration, typically injection or infusion.
9. Specialty Pharmacy – a closed door pharmacy that is trained to dispense specialty medications.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:

Specific intravenous and injectable drugs must meet applicable medical necessity criteria for coverage. If these criteria are met, this coverage policy will be used to define which medications must be obtained through a Specialty Pharmacy. The Specialty Pharmacy will distribute the patient specific medication directly to the providers office or facility where the medication will be prepared and administered to the patient. This policy is effective for the exchange, commercial, and ASO lines of business, excluding PEBTF and medical benefit only ASOs.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

This policy lists medications that are suitable for distribution from a specialty pharmacy to a prescribing provider or facility to administer.

Prescribing providers or facilities

The prescribing provider must order a specialty medication from a contracted preferred Specialty pharmacy. The prescribing provider or facility will be responsible for a well-trained staff to admix and administer the medication safely to the patient. The specialty pharmacy will be able to answer any questions they may have regarding the specialty medication. The prescribing provider or facility can bill for the administration of the medication only. The prescribing provider or facility may not bill for the full cost of the medication because they did not purchase it or dispense from their own supply (as would be the practice of buy and bill).

If prior authorization is needed, the prescribing provider must submit the prior authorization request including relevant chart information to the health plan for review.

Specialty Pharmacy

The specialty pharmacy will dispense the member specific medication and bill Geisinger Health Plan. The specialty pharmacy will then dispense (ship out/deliver) the medication directly to the provider's office or facility for administration.

Medications are subject to cost-sharing and utilization management, as outlined in formulary and/or benefit documentation.

The specialty pharmacy will dispense (ship out/deliver) the prescribed medication to the administering provider or facility with patient-specific labeling (after prior authorization is approved, if applicable). The specialty pharmacy must package the drug for delivery to ensure product integrity and temperature control of the medications in transit. The drug shipment will not include the IV bags, lines, and other administrative supplies. These will need to be issued/supplied by the administering provider or facility.

To mitigate wastage, the specialty pharmacy will need to do the following two steps when dispensing:

1. If the drug is to be admixed or compounded, it is their responsibility to send out a dosage that is the smallest amount possible above the prescribed amount. This will be monitored and addressed with the specialty pharmacies if wastage discrepancies are noticed.
2. Verify the date of administration with the member and provider or facility, as the claim will be processed at the time of dispense (not the date of administration). The drug will not be able to be returned after it is dispensed, if not used for that specific member.

The specialty pharmacy is responsible for delivering the medication to the administering facility or provider's office in time for the patient's administration appointment. In the case of same day treatment changes, a provider's office or facility may request a one-time emergency reimbursement from the health plan by contacting the customer call center so that the member may obtain their infusion and there is no delay in therapy. The one-time authorization is only valid the same day as the treatment change and the request for the emergency authorization. If approved, the drug would be reimbursed to the office or facility at the contracted rate of the specialty pharmacy.

LIMITATIONS:

- If the above conditions are not met, but the administration location is determined by the Health Plan to be a least costly administration site, the provider may be approved for direct reimbursement of the administered medication.
- Home infusion companies administering the intravenous or injectable drug in a home or suite setting may opt, but are not required, to supply the administered drug via specialty pharmacy.

LINE OF BUSINESS:

This policy does not apply to the Medicare, Medicaid, CHIP, PEBTF, or medical benefit only ASO lines of business. Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/1/23

Revised: 8/12/24 (Exclude Medicaid/CHIP, add Tecentriq, Bavencio, Libtayo, Jemperli, Imfinzi, Padcev, Opdivo, Yervoy, Opdualag, Zynyz, Tevimbra, Loqtorzi, Imjudo), 8/19/24 (add Dysport, Daxxify, Xeomin, Botox, Myobloc [to be effective 11/1/24]), 12/19/24 (add Darzalex/Darzalex Faspro, Halaven, Enhertu, Poteligeo, Gazyva, Sandostatin LAR, Vactibix, Polivy, Cyramza, Rituxan/Rituxan Hycela, Herceptin, LOB table, taglines), 1/14/25 (add Aripiprazole, Aripiprazole lauroxil, Nulojix, Xiaflex, Fluphenazine deconate, Haloperidol deconate, Olanzapine, Paliperidone, Krystexxa, Risperidone, Nplate, Tevimbra [to be effective 6/1/25]), add Kadcyra, Rylaze, Beleodaq, Adcetris, Bortezomib, Kyprolis, Vyxeos, Besponsa, Istodax, Opdivo Qvantig [to be effective 9/1/25])

Reviewed: