"What's New" Medical Pharmaceutical Policy November 2025 Updates

The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 352.0 Lynozyfic (linvoseltamab-gcpt) – New Policy

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Lynozyfic is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

MBP 351.0 Encelto (revakinagene taroretcel-lwey) – New Policy

- Medical record documentation that Encelto is prescribed by an ophthalmologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of idiopathic macular telangiectasia type 2 (MacTel) type 2 as evident by the following:
    - Evidence of fluorescein leakage AND one of the following:
        - Hyperpigmentation outside a 500-micron radius from the fovea center,
        - Retinal opacification,
        - Crystalline deposits,
        - Right-angle vessels,
        - Or inner/outer lamellar cavities **AND**
- Medical record documentation that the patient has not previously received an Encelto implant in the requested eye **AND**
- Medical record documentation of photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm2 **AND**
- Medical record documentation of best corrected visual acuity (BCVA) of 54-letter score or better (20/80 or better) **AND**
- Medical record documentation that the member does NOT have neovascular MacTel type 2

AUTHORIZATION DURATION: One (1) time approval per eye per lifetime. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

MBP 221.0 Monjuvi (tafasitamab-cxix) – Updated Policy

1. **Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)**
    - Medical record documentation of age greater than or equal to 18 years **AND**
    - Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
    - Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma **AND**
    - Medical record documentation that the member is not eligible for autologous stem cell transplant (ASCT) **AND**
    - Medical record documentation that Monjuvi will be used in combination with Revlimid (lenalidomide)

2. **Relapsed or Refractory Follicular Lymphoma (FL)**
   - Medical record documentation of age greater than or equal to 18 years **AND**
   - Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
   - Medical record documentation of relapsed or refractory follicular lymphoma (FL) **AND**
   - Medical record documentation that Monjuvi will be used in combination with lenalidomide (Revlimid) and rituximab

MBP 268.0 Amvuttra (vutrisiran) – Updated Policy

- Prescription written by or in consultation with a neurologist, cardiologist, board-certified medical geneticist, or specialist with experience in the treatment of hereditary or wild-type transthyretin-mediated amyloidosis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Amvuttra will not be used in combination with other RNA interference treatment **AND**

For hereditary transthyretin-mediated amyloidosis (hATTR):

- Medical record documentation of diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND one of the following:
  - Biopsy of tissue/organ to confirm amyloid presence **OR**
  - A clinical manifestation typical of hATTR (Neuropathy and/or CHF) without a better alternative explanation **AND**
- One of the following:
  - Medical record documentation of Amvuttra being used to treat polyneuropathy **AND**
  - Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden

  OR
  - Medical record documentation of Amvuttra being used for cardiomyopathy to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits

OR

For wild-type transthyretin-mediated amyloidosis (wtATTR):

- Medical record documentation of diagnosis of wild-type transthyretin-mediated amyloidosis as confirmed by genetic testing **AND**
- Medical record documentation Amvuttra is being used for cardiomyopathy to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visit

MBP 122.0 Sivextro (tedizolid phosphate) IV – Updated Policy

- ~~Medical record documentation that patient is ≥ 12 years of age **AND**~~
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis which has been diagnosed and documented with Infectious Disease consultation **AND**
- Medical record documentation of a prescribed dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR**

- If Sivextro was initiated during an inpatient stay, medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

AUTHORIZATION LIMIT: If approved, Sivextro IV will be authorized for a maximum of 6 daily doses.

MBP 119.0 Keytruda (pembrolizumab) – Updated Policy

1. **Head and Neck Squamous Cell Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
    - A diagnosis of Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic **AND**
    - Disease progression on or after platinum-containing chemotherapy **AND**
    - Keytruda is being used as a single agent.

OR

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma **AND**
- Keytruda is being used as a first-line treatment **AND**
- Keytruda is being used as a single agent **AND**
- Tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test

OR

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma **AND**
- Keytruda is being used as a first-line treatment **AND**
- Keytruda is being administered in combination with platinum chemotherapy and fluorouracil (FU)

OR

- A diagnosis of resectable locally advanced Head and Neck Squamous Cell Carcinoma **AND**
- Tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test **AND**
- Keytruda is being used as a single agent for neoadjuvant treatment, followed by adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent

2. **Gastric Cancer**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that Keytruda will be used as first-line treatment **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of locally advanced unresectable or metastatic HER-2 positive gastric or gastroesophageal junction adenocarcinoma **AND**
    - Medical record documentation that tumors express PD-L1 (CPS≥1) as approved by an FDA approved test **AND**
    - Medical record documentation that Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy

OR

- Medical record documentation of locally advanced unresectable or metastatic HER-2 negative gastric or gastroesophageal junction (GEJ) adenocarcinoma **AND**
- Medical record documentation that tumors express PD-L1 (CPS≥1) as approved by an FDA approved test **AND**

- Medical record documentation that Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

For neoadjuvant/adjuvant treatment of head and neck squamous cell carcinoma:
Initial approval will be for 6 months. Additional approval will be for up to an additional 12 months or less if determined medically appropriate by the reviewing provider and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

- Authorization for the treatment of neoadjuvant/adjuvant treatment of head and neck squamous cell carcinoma should not exceed the approved treatment duration of 6 weeks of neoadjuvant treatment and 12 months of adjuvant treatment.

For requests exceeding the above limits, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

The following policies were reviewed with no changes:

- MBP 289.0 Elfabrio
- MBP 264.0 Enjaymo
- MBP 291.0 Lamzede
- MBP 39.0 Naglazyme
- MBP 292.0 Omisirge
- MBP 293.0 Qalsody
- MBP 91.0 Yervoy
- MBP 301.0 Elrexfio

The following policies were retired:

- MBP 102.0 Synribo

The following policy updates and reviews apply to Commercial, Marketplace, TPA, and Medicare GHP members only:

MBP 350.0 Posfrea (palonosetron) – New Policy

- Medical record documentation that Posfrea is being used for prevention of acute or delayed nausea and vomiting associated with initial and repeat courses of moderately or highly emetogenic cancer chemotherapy **AND**
- Medical record documentation of therapeutic failure, intolerance, or contraindication to palonosetron (generic Aloxi)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation that member continues to receive a moderately to highly emetogenic cancer chemotherapy regimen AND has been benefiting from Posfrea.

MBP 295.0 Briumvi (ublituximab-xiiy) – Updated Policy

- Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation that Briumvi is prescribed by a neurologist **AND**
- Medical record documentation of a Hepatitis B Screening **AND**
- Medical record documentation that member has failed, is intolerant to, or has a contraindication to a preferred rituximab product **AND**

- If intolerant to the preferred rituximab product, documentation of previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion.

MBP 330.0 Tremfya (guselkumab) – Updated Policy

Crohn's Disease

- Medical record documentation that Tremfya is prescribed by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of Tremfya 200 mg /20 mL vials for IV infusion are being prescribed for induction therapy at weeks 0, 4, and 8 **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** immunomodulators (e.g. azathioprine and 6-mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior

MBP 155.0 Ocrevus or Ocrevus Zunovo & Part B Step Therapy 2026 [to be effective 1/1/26] – Updated Policy

Ocrevus (ocrelizumab) or Ocrevus Zunovo (ocrelizumab/hyaluronidase-ocsq) will be considered medically necessary for the commercial, exchange, CHIP, and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation Ocrevus or Ocrevus Zunovo is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- One of the following:
    - Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR**
    - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND

- For members with a diagnosis of a relapsing form of multiple sclerosis
    - Medical record documentation that member has failed, is intolerant to, or has a contraindication to a preferred rituximab product **AND**
    - If intolerant to the preferred rituximab product, documentation of previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion.

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

QUANTITY LIMIT:

Ocrevus:

- Initial authorization: 12-month duration with quantity limit of 3 doses
- Re-authorization: 12-month duration with quantity limit of 2 doses

Ocrevus Zunovo:

- Initial authorization and Re-authorization: 12-month duration with quantity limit of 2 doses

MBP 300.0 Medical Benefit Drug Optimization Program [to be effective 3/1/26] – Updated Policy

This policy applies to these medications:

1. AbobotulinumtoxinA (Dysport)
2. Ado-Trastuzumab Emtansine (Kadcyla)
3. Amivantamab (Rybrevant)
4. Aripiprazole (Abilify Maintena, Abilify Asimtufii)
5. Aripiprazole lauroxil (Aristada Initio, Aristada)
6. Arsenic Trioxide (Trisenox)
7. Asparaginase (Erwinia [Recombinant]) (Rylaze)
8. Atezolizumab (Tecentriq)
9. Avelumab (Bavencio)
10. Belatacept (Nulojix)
11. Belinostat (Beleodaq)
12. Blinatumomab (Blincyto)
13. Brentuximab Vedotin (Adcetris)
14. Bortezomib
15. Cabazitaxel (Jevtana)
16. Capsaicin (Qutenza)
17. Carfilzomib (Kyprolis)
18. Cemiplimab (Libtayo)
19. Collagenase (Xiaflex)
20. Datopotamab Deruxtecan (Datroway)
21. Daunorubicin and Cytarabine (Liposomal) (Vyxeos)
22. Daratumumab (Darzalex)
23. Daratumumab and Hyaluronidase (Darzalex Faspro)
24. DaxibotulinumtoxinA (Daxxify)
25. Donanemab (Kisunla)
26. Dostarlimab (Jemperli)
27. Durvalumab (Imfinzi)
28. Elotuzumab (Empliciti)
29. Elranatamab (Elrexfio)
30. Epcoritamab (Epkinly)
31. Eribulin (Halaven)
32. Enfortumab Vedotin (Padcev)
33. Fam-Trastuzumab Deruxtecan (Enhertu)
34. Ferric Carboxymaltose (Injectafer)
35. Ferric Derisomaltose (Monoferric)
36. Fluphenazine deconate
37. Fosdenopterin (Nulibry)
38. Gemtuzumab Ozogamicin (Mylotarg)
39. Haloperidol deconate
40. Imetelstat (Rytelo)
41. IncobotulinumtoxinA (Xeomin)
42. Inotuzumab Ozogamicin (Besponsa)
43. Ipilimumab (Yervoy)
44. Irinotecan liposomal (Onivyde)
45. Isatuximab (Sarclisa)
46. Lanreotide (Somatuline Depot)
47. Lecanemab (Leqembi)
48. Loncastuximab Tesirine (Zynlonta)
49. Lurbinectedin (Zepzelca)
50. Luspatercept (Reblozyl)
51. Margetuximab (Margenza)
52. Mirvetuximab Soravtansine (Elahere)
53. Mogamulizumab (Poteligeo)
54. Mosunetuzumab (Lunsumio)
55. Naxitamab (Danyelza)
56. Necitumumab (Portrazza)
57. Nivolumab (Opdivo)
58. Nivolumab and hyaluronidase-nvhy (Opdivo Qvantig)
59. Obinutuzumab (Gazyva)
60. Octreotide (Sandostatin LAR)
61. Olanzapine (Zyprexa Relprevv)
62. OnabotulinumtoxinA (Botox)
63. Paliperidone (Invega Sustenna, Invega Hafyera, Invega Trinza)
64. Panitumumab (Vectibix)
65. Pasireotide (Signifor LAR)
66. Pegloticase (Krystexxa)
67. Pembrolizumab (Keytruda)
68. Polatuzumab Vedotin (Polivy)
69. Ramucirumab (Cyramza)
70. Relatlimab and nivolumab (Opdualag)
71. Retifanlimab (Zynyz)
72. RimabotulinumtoxinB (Myobloc)
73. Risperidone (Perseris, Risperdal Consta, Rykindo, Uzedy)
74. Rituximab (Rituxan)
75. Rituximab and Hyaluronidase (Rituxan Hycela)
76. Romidepsin (Istodax)
77. Romiplostim (Nplate)
78. Siltuximab (Sylvant)
79. Sipuleucel-T (Provenge)
80. Sutimlimab (Enjaymo)
81. Tafasitamab (Monjuvi)

82. Tagraxofusp (Elzonris)
83. Tarlatamab (Imdelltra)
84. Tebentafusp (Kimmtrak)
85. Temsirolimus (Torisel)
86. Telisotuzumab Vedotin (Emrelis)
87. Thiotepa (Tepadina)
88. Tislelizumab (Tevimbra)
89. Tisotumab Vedotin (Tivdak)
90. Toripalimab (Loqtorzi)
91. Trabectedin (Yondelis)
92. Trastuzumab (Herceptin)
93. Tremelimumab (Imjudo)
94. Zolbetuximab (Vyloy)

MBP 76.0 Actemra IV (tocilizumab), Tofidence IV (tocilizumab-bavi), Tyenne IV (tocilizumab-aazg) – Updated Policy

1. Adults with moderate to severe rheumatoid arthritis
   - Medical record documentation that member is 18 years of age or greater **AND**
   - Prescription written by a rheumatologist **AND**
   - Physician provided documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis) **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of a therapeutic failure on, contraindication to or intolerance to 12 weeks of a preferred adalimumab poduct ~~Humira~~*, Rinvoq*, Enbrel* OR Xeljanz* **AND**
   - For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tofidence*) and tocilizumab-aazg (Tyenne*).

   *Requires prior authorization

2. Active polyarticular juvenile idiopathic arthritis (PJIA)
   - Medical record documentation that member is 2 years of age or greater **AND**
   - Prescription is written by a rheumatologist **AND**
   - Medical record documentation of a diagnosis active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Physician provided documentation of a therapeutic failure on, contraindication to or intolerance to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of juvenile idiopathic arthritis or juvenile rheumatoid arthritis ~~4 month trial of Humira*~~ **AND**
   - For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tofidence*) and tocilizumab-aazg (Tyenne*).

The following policies were reviewed with no changes:

- MBP 47.0 Lucentis, Byooviz, and Cimerli
- MBP 253.0 Vabysmo
- MBP 202.0 Evenity
- MBP 242.0 Evkeeza
- MBP 240.0 Fensolvi
- MBP 265.0 Igalmi
- MBP 57.0 Tysabri
- MBP 269.0 Qutenza
- MBP 299.0 Aponvie
- MBP 59.0 White Blood Cell Stimulating Factors
- MBP 316.0 Izervay

- MBP 278.0 Syfovre
- MBP 251.0 Beovu
- MBP 49.0 Erythropoeitin and Darbepoetin
- MBP 130.0 Mircera
- MBP 84.0 Berinert
- MBP 85.0 Cinryze
- MBP 5.0 Remicade, Inflectra, Renflexis, Avsola