"What's New" Medical Pharmaceutical Policy October 2024 Updates

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

The following policies were reviewed with no changes:

- MBP 2.0 Synagis
- MBP 289.0 Elfabrio
- MBP 204.0 Triptodur

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

MBP 278.0 Syfovre (pegcetacoplan) – Updated Policy

- Medical record documentation of the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **AND**
- Medical record documentation of a confirmed diagnosis of geographic atrophy (GA) using imagining modalities, including but not limited to fundus autofluorescence (FAF), fundus photography, or optical coherence tomography (OCT) **AND**
- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of 20/320 or better (for example 20/200, 20/80, 20/70, etc) in the eye(s) to be treated with Syfovre **AND**
- Medical record documentation that Syfovre will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to AMD (i.e. Izervay)
- ~~For new starts only: Medical record documentation of the absence of active, or history of, choroidal neovascularization* (CNV) in the eye(s) to be treated with Syfovre.~~

~~*Note: Age-related macular degeneration (AMD) with CNV is often referred to as exudative AMD (eAMD), neovascular AMD (nAMD), or wet AMD (wAMD).~~

AUTHORIZATION DURATION: ~~Approvals will be given for a lifetime duration.~~ Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of better than 20/320 (for example 20/200, 20/80, 20/70, etc.) in the eye(s) being treated with Syfovre **AND**
- Medical record documentation of the absence, or resolution, of Retinal Vasculitis, Retinal Vascular Occlusion, and/or active Intraocular Inflammation (including but not limited to: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare) **AND**
- Medical record documentation that Syfovre will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to AMD (i.e. Izervay) **AND**
- One of the following:
  - Medical record documentation of the absence of active choroidal neovascularization (CNV), or neovascular (wet) Age Related Macular Degeneration (nAMD) in the Syfovre-treated eye(s) **OR**
  - Medical record documentation that the member's active CNV, or nAMD is NOT worsening **OR**
  - Medical record documentation of rationale for continued use in the setting of worsening CNV, or nAMD (eg. The benefits of Syfovre outweigh the risks of Syfovre administration)

MBP 316.0 Izervay (avacincaptad pegol) – Updated Policy

- Medical record documentation of the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **AND**
- Medical record documentation of a confirmed diagnosis of GA using imagining modalities, including but not limited to fundus autofluorescence (FAF), fundus photography, or optical coherence tomography (OCT) **AND**
- ~~For new starts only: Medical record documentation of the absence of active, or history of, choroidal neovascularization* (CNV) in the eye(s) to be treated with Izervay **AND**~~
- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of 20/320 or better (for example 20/200, 20/80, 20/70, etc) in the eye(s) to be treated with Izervay **AND**
- Medical record documentation that Izervay will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to age-related macular degeneration (AMD) (e.g. Syfovre)

~~*Note: Age-related macular degeneration (AMD) with CNV is often referred to as exudative AMD (eAMD), neovascular AMD (nAMD), or wet AMD (wAMD).~~

AUTHORIZATION DURATION: ~~12 Months~~ Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of better than 20/320 (for example 20/200, 20/80, 20/70, etc.) in the eye(s) being treated with Izervay **AND**
- Medical record documentation that Izervay will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to AMD (i.e. Syfovre) **AND**
- One of the following:
  - Medical record documentation of the absence of active choroidal neovascularization (CNV), or neovascular (wet) Age Related Macular Degeneration (nAMD) in the Izervay-treated eye(s) **OR**
  - Medical record documentation that the member's active CNV, or nAMD is NOT worsening **OR**
  - Medical record documentation of rationale for continued use in the setting of worsening CNV, or nAMD (eg. The benefits of Izervay outweigh the risks of Izervay administration)

MBP 181.0 Site of Care Review Guidelines for Infusion Drugs and Specialty Medications – Updated Policy

To provide a policy of coverage regarding the use of hospital-based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection. This policy applies to these medications:

1. Abatacept (Orencia IV)
2. ADAMTS13 [Recombinant] (Adzynma)
3. Agalsidase Beta (Fabrazyme)
4. Alglucosidase Alfa (Lumizyme)
5. Alpha1-Proteinase Inhibitor [Human] products
6. Anifrolumab-fnia (Saphnelo)
7. Avalglucosidase alfa-ngpt (Nexviazyme)
8. Belimumab (Benlysta IV)
9. Benralizumab (Fasenra)
10. Beremagene Geperpavec (Vyjuvek)
11. Burosumab (Crysvita)
12. C1 esterase Inhibitor [Human] (Cinryze)
13. Canakinumab (Ilaris)

14. Casimersen (Amondys 45)
15. Certolizumab (Cimzia)
16. Cipaglucosidase alfa (Pombiliti)
17. Crizanlizumab (Adakveo)
18. Denosumab (Prolia, Xgeva)
19. Eculizumab (Soliris)
20. Edaravone (Radicava)
21. Efgartigimod Alfa (Vyvgart & Vyvgart Hytrulo)
22. Elapegademase-lvlr (Revcovi)
23. Elosulfase alfa (Vimizim)
24. Eptinezumab (Vyepti)
25. Eteplirsen (Exondys 51)
26. Evinacumab (Evkeeza)
27. Galsulfase (Naglazyme)
28. Givosiran (Givlaari)
29. Golodirsen (Vyondys 53)
30. Golimumab (Simponi Aria)
31. Idursulfase (Elaprase)
32. Immune Globulin (IVIG)
33. Imiglucerase (Cerezyme)
34. Inclisiran (Leqvio)
35. Inebilizumab (Uplizna)
36. Infliximab & infliximab biosimilar products
37. Laronidase (Aldurazyme)
38. Lenacapavir (Sunlenca)
39. Lumasiran (Oxlumo)
40. Mepolizumab (Nucala)
41. Natalizumab (Tysabri)
42. Ocrelizumab (Ocrevus)
43. Olipudase alfa-rpcp (Xenpozyme)
44. Omalizumab (Xolair)
45. Pegunigalsidase Alfa (Elfabrio)
46. Pozelimab (Veopoz)
47. Patisiran (Onpattro)
48. Ravulizumab (Ultomiris)
49. Romosozumab (Evenity)
50. Rozanolixizumab (Rystiggo)
51. Sebelipase alfa (Kanuma)
52. Secukinumab (Cosentyx IV)
53. Sutimlimab (Enjaymo)
54. Taliglucerase alfa (Elelyso)
55. Teprotumumab (Tepezza)
56. Testosterone udecanoate (Aveed)
57. Tezepelumab (Tezspire)
58. Tildrakizumab (Ilumya)
59. Tocilizumab (Actemra IV)
60. Ublituximab-xiiy (Briumvi)
61. Ustekinumab (Stelara)
62. Vedolizumab (Entyvio)
63. Velaglucerase alfa (Vpriv)
64. Velmanase alfa (Lamzede)
65. Vestronidase alfa-vjbk (Mepsevii)
66. Viltolarsen (Viltepso)
67. Vutrisiran (Amvuttra)

MBP 206.0 Khapzory (Levoleucovorin) and 2025 Part B Step Therapy Drug List & Criteria – Updated Policy, to be effective 1/15/2025

Khapzory (Levoleucovorin) will be considered medically necessary for all ~~the commercial, exchange, CHIP, and Medicaid~~ lines of business when ALL of the following criteria are met:

- Medical record documentation of intolerance to or contraindication to preferred levoleucovorin calcium products.

Preferred products: levoleucovorin calcium vial, powder for reconstitution, levoleucovorin calcium vial, solution

MBP 76.0 Actemra IV (tocilizumab) – Updated Policy

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 (Tolfidence) and tocilizumab-aazg (Tyenne).

MBP 130.0 Mircera (methoxy polyethylene glycol-epoetin beta) – Updated Policy

For initial authorization in pediatric patients:

- Medical record documentation of age 3 months ~~5 years~~ or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients on dialysis and patients not on dialysis **AND**

- Medical record documentation that patient's hemoglobin has stabilized on and patient is converting to Mircera from another erythropoiesis-stimulating agent **AND**
- Hemoglobin (Hgb) less than 11 g/dL for new starts **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

For continuation of therapy in adult and pediatric patients:

- ~~Medical record documentation of age 18 years or greater **AND**~~
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis **AND**
- Hemoglobin (Hgb) less than 11 g/dL for continuation of therapy **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

GENERAL GUIDANCE:

- For continuation of therapy, a repeat Hgb no greater than 3 months old should be submitted.
- In individuals whose Hgb is greater than or equal to 12gm/dL or rises by 1gm/dL in any two-week period, additional doses should be withheld or reduced (Except when being used for reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery).
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/ or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/mL and transferrin saturation is less than 20 percent

MBP 267.0 Skyrizi – Updated Policy

Ulcerative Colitis

- Medical record documentation that Skyrizi is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one conventional systemic therapy* (e.g. corticosteroids, immunomodulators such as azathioprine, 6 mercaptopurine, cyclosporine, tacrolimus) OR medical record documentation of a therapeutic failure on or intolerance to one prior biologic therapy **AND**
- Medical record documentation of two Skyrizi 600 mg /10 mL vials for IV infusion are being prescribed for induction therapy at weeks 0, 4, and 8.

The following policies were reviewed with no changes:

- MBP 49.0 Erythropoietin and Darbepoetin Therapy
- MBP 59.0 White Blood Cell Stimulating Factors
- MBP 299.0 Aponvie
- MBP 251.0 Beovu

The following policies were retired:

- MBP 24.0 Aloxi
- MBP 104.0 Emend IV