Formulary Updates

DEFINITIONS

Formulary	These drugs are included in Mass General Brigham's covered drug list.
Non-Formulary	These drugs are not included in Mass General Brigham's formulary. The plan would only cover formulary alternatives. Providers can request Non-Formulary drugs as an exception, and the plan would require trial of all appropriate formulary alternatives prior to approving coverage of a Non-Formulary drug. If a Non-Formulary drug is approved, the member's cost sharing would be the highest tier.
Preferred	These drugs are on Mass General Brigham's formulary and offer a lower cost to members.
Non-Preferred	These drugs are on Mass General Brigham's formulary but offer a higher cost to members.
Excluded	Mass General Brigham does not cover these drugs. Members will receive a denial for all Excluded drug requests.

Updates for Commercial Members

PHARMACY BENEFIT

Effective 01/01/2027
The following changes are being made to the listed medications and classes on the pharmacy benefit:

Farxiga, Xigduo XR	• Effective 1/1/2027, brand formulations of Farxiga and Xigduo XR will be nonformulary. • Generic dapagliflozin and generic dapagliflozin/metformin extended-release will continue to be covered without prior authorization. • Members currently filling brand Farxiga and brand Xigduo XR will require prior authorization to continue coverage of the brands on or after 1/1/2027.
Qsymia	• Effective 1/1/2027, brand formulations of Qsymia will be nonformulary. • Generic phentermine/topiramate extended-release will continue to be covered with a quantity limit. • Members currently filling brand Qsymia will require prior authorization to continue coverage of the brand on or after 1/1/2027.
Jynarque	• Effective 1/1/2027, brand Jynarque will be nonformulary, and generic equivalents of Jynarque (tolvaptan) will be covered with a quantity limit. • Members currently filling brand Jynarque will require prior authorization to continue coverage of the brand on or after 1/1/2027.

Stimulant Step Therapy Program	• Effective 1/1/2027, Quillichew ER will be nonformulary and will be removed from the stimulant step therapy program and policy. • Members currently on Quillichew ER will require prior authorization to continue coverage on or after 1/1/2027.
Imiquimod	• Effective 1/1/2027, imiquimod 3.75% cream will be nonformulary. Members currently administering imiquimod 3.75% cream will require prior authorization to continue coverage on or after 1/1/2027. • With imiquimod 3.75% moving to nonformulary status, the Imiquimod Agents policy is being retired. • Imiquimod 5% cream will continue to be covered without prior authorization.
Ophthalmic NSAIDs	• Effective 1/1/2027, bromfenac 0.09% and 0.07% ophthalmic solution will be removed from the ophthalmic NSAIDs step therapy program and policy, as they are moving to nonformulary status. • Members currently administering bromfenac 0.09% or 0.07% ophthalmic solution will require prior authorization to continue coverage on or after 1/1/2027. • With bromfenac 0.09% and 0.07% ophthalmic solution moving to nonformulary status, the Ophthalmic NSAIDs policy is being retired.
Topical Corticosteroids	• Effective 1/1/2027, fluticasone 0.05% lotion will be removed from the step therapy policy, as the agent is moving to nonformulary status. • Members currently administering fluticasone 0.05% lotion will require prior authorization to continue coverage on or after 1/1/2027.
Altabax	• Effective 1/1/207, the policy for Altabax is being retired as this product has been discontinued.
Denosumab Products	• All denosumab products will continue to require prior authorization. • Effective 1/1/2027, Jubbonti and Wyost will be moved to the nonpreferred specialty tier and will be considered nonpreferred denosumab products. • Enoby and Stoboclo will continue to be the preferred Prolia biosimilars, while Osenvelt and Xtrenbo will continue to be the preferred Xgeva biosimilars. • Initial and reauthorization criteria for Prolia and all nonpreferred Prolia biosimilars (including Jubbonti) will be updated to include a required trial and failure with Enoby AND Stoboclo. • Initial and reauthorization criteria for Xgeva and all nonpreferred Xgeva biosimilars (including Wyost) will be updated to include a required trial and failure with Xtrenbo AND Osenvelt. • Members currently utilizing Jubbonti or Wyost will require a new authorization to continue coverage for their current agent on or after 1/1/2027. Members on Jubbonti will not require a new prior authorization for Enoby or Stoboclo for the duration of their existing authorization. Members on Wyost will not require a new prior authorization for Osenvelt or Xtrenbo for the duration of their existing authorization.

	• To ensure continuity of care, it is recommended providers write new prescriptions for one of the preferred products (Enoby, Stoboclo, Xtrenbo, Osenvelt).
Xeljanz, Xeljanz XR	• Effective 1/1/2027, brand formulations of Xeljanz and Xeljanz XR will be moved to nonformulary status. The generic formulations will be added to the formulary with prior authorization and quantity limit. • Members currently filling brand Xeljanz and brand Xeljanz XR can switch to the generic on or after 1/1/2027 without a new authorization and can fill the generic formulations for the duration of their existing authorization. • Members currently filling brand Xeljanz or brand Xeljanz XR will require prior authorization to continue coverage of the brand formulations on or after 1/1/2027.
Adalimumab Products	• Effective 1/1/2027, the biosimilars adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab products. Prior authorization and quantity limit restrictions will apply. • Also effective 1/1/2027, Humira and all of its remaining biosimilars will be moved to nonformulary status. Adalimumab-aaty, adalimumab-adaz and Hadlima will be the only adalimumab products on the formulary. • Members currently utilizing Humira or a nonformulary biosimilar will require a new authorization to continue coverage of their current agent on or after 1/1/2027. They will not require a new prior authorization for the preferred adalimumab products (adalimumab-aaty, adalimumab-adaz, or Hadlima) for the duration of their existing authorization. • To ensure continuity of care, it is recommended that providers write new prescriptions for one of the preferred adalimumab products (adalimumab-aaty, adalimumab-adaz, Hadlima). • The Adalimumab Products policy is being updated to reflect these coverage changes.
Tocilizumab Products	• Tyenne will continue to be a preferred tocilizumab product. Effective 1/1/2027, Avtozma will also be a preferred tocilizumab product. Both will continue to be covered on the nonpreferred specialty tier with prior authorization and quantity limit. • Actemra and Tofidence will continue to be nonpreferred tocilizumab products. They will also continue to be covered on the nonpreferred specialty tier with prior authorization and quantity limit. • Initial and reauthorization criteria for Actemra and Tofidence will be updated to include a required trial and failure with Avtozma AND Tyenne. • Members currently utilizing Actemra or Tofidence will require a new authorization to continue coverage of their current agent on or after 1/1/2027. They will not require a new prior authorization for the preferred tocilizumab products for the duration of their existing authorization. • Criteria for all tocilizumab products will continue to include diagnosis-specific biologic trial and failure requirements.

	• The Tocilizumab Products policy will also be updated to indicate that adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab trial options for rheumatoid arthritis and polyarticular juvenile idiopathic arthritis (pJIA). Additionally, Xeljanz products will be removed as a previous trial option for pJIA and rheumatoid arthritis.
Sotyktu	• Sotyktu will be nonformulary effective 1/1/2027. The Sotyktu policy will be retired. • Members currently utilizing Sotyktu will require new authorizations to continue coverage on or after 1/1/2027.
Cosentyx SC	• Cosentyx SC will be nonformulary effective 1/1/2027. The Cosentyx SC policy will be retired. • Members currently utilizing Cosentyx SC will require new authorizations to continue coverage on or after 1/1/2027.
Entyvio SC	• Effective 1/1/2027, the criteria for Entyvio SC are being updated to indicate that adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab trial options for ulcerative colitis and Crohn's disease. • Additionally, Xeljanz products will be removed as a previous trial option for the treatment of ulcerative colitis.
Ilumya	• Effective 1/1/2027, the criteria for Ilumya are being updated to indicate that adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab trial options for plaque psoriasis. • Additionally, Sotyktu will be removed as a previous trial option for plaque psoriasis.
Kineret, Olumiant	• Effective 1/1/2027, the criteria for Kineret and Olumiant are being updated to indicate that adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab trial options for rheumatoid arthritis. • The criteria will also be updated to indicate that Avtozma and Tyenne will be the preferred tocilizumab trial options for rheumatoid arthritis. • Additionally, Xeljanz products will be removed as a previous trial option for the treatment of rheumatoid arthritis.
Kevzara	• Effective 1/1/2027, the criteria for Kevzara are being updated to indicate that adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab trial options for rheumatoid arthritis and polyarticular juvenile idiopathic arthritis (pJIA). • The criteria are also being updated to indicate that Avtozma and Tyenne will be the preferred tocilizumab trial options for rheumatoid arthritis and pJIA. • Additionally, Xeljanz products are being removed as a previous trial option for the treatment of rheumatoid arthritis and pJIA.
Orencia	• Effective 1/1/2027, the criteria for Orencia are being updated to indicate that adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab trial options for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (pJIA), and psoriatic arthritis. • Criteria are also being updated to remove Xeljanz products as a previous trial option for the treatment of pJIA, psoriatic arthritis, and rheumatoid arthritis.

<table>
<tr><td></td><td>

- Lastly, the criteria for psoriatic arthritis are being updated to remove Sotyktu as a previous trial option.

</td></tr>
<tr><td>Siliq</td><td>

- Effective 1/1/2027, criteria for Siliq are being updated to indicate that adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab trial options for plaque psorisis.
- Additionally, criteria are being updated to remove Sotyktu as a previous trial option for plaque psoriasis. Criteria will continue to include a required trial and failure with Bimzelx and Taltz and two other preferred immunomodulators.

</td></tr>
<tr><td>Zeposia</td><td>

- Effective 1/1/2027, criteria for Zeposia for the treatment of ulcerative colitis are being updated to indicate that adalimumab-aaty, adalimumab-adaz, and Hadlima will be the preferred adalimumab trial options.
- Additionally, Xeljanz products are being removed as a previous trial option for the treatment of ulcerative colitis.

</td></tr>
<tr><td>PACT Act Drug Updates</td><td>

- Effective 1/1/2027, the following drugs will no longer be selected in accordance with the PACT Act:
  - Montelukast tablet/chewable tablet/granules
  - Atorvastatin tablet
  - Repatha injection
- The drugs listed above will default to the copayment for their respective tier.

</td></tr>
<tr><td>Jardiance</td><td>

- Effective 1/1/2027, Jardiance is being removed as a drug taking a $0 cost share on the ConnectorCare chronic conditions list. It is being replaced with generic dapagliflozin tablet.

</td></tr>
<tr><td>Dry Eye Disease</td><td>

- Brand Restasis, Restasis Multidose, and Xiidra will continue to be preferred. Prior authorization restrictions and existing criteria will continue to apply.
- Effective 1/1/2027, Miebo and Tryptyr will also be preferred dry eye disease agents. Prior authorization restrictions will apply. Initial criteria will require diagnosis and trial and failure or intolerance to artificial tears. Reauthorization criteria will require positive response to therapy.

</td></tr>
<tr><td>Drugs Moving to Nonformulary Status</td><td>

- The drugs listed in the table below are moving to nonformulary status. They will be removed from the pharmacy formulary. Prior authorization will be required to continue treatment on or after 1/1/2027.

<table>
<tr><th colspan="3">Drug Names</th></tr>
<tr><td>Armour thyroid tablet</td><td>Brinzolamide 1% ophthalmic suspension</td><td>Bromfenac 0.07% ophthalmic solution</td></tr>
<tr><td>Bromfenac 0.09% ophthalmic solution</td><td>Captopril tablet</td><td>Cimetidine tablet</td></tr>
<tr><td>Dutasteride/tamsulosin capsule</td><td>Evexithroid tablet</td><td>Fluticasone 0.05% lotion</td></tr>
<tr><td>Hydroxyzine pamoate 100 mg capsule</td><td>Imiquimod cream 3.75%</td><td>Ketoprofen 50 mg capsule</td></tr>
<tr><td>Loteprednol etabonate 0.2% suspension</td><td>Megestrol suspension 625 mg/5 mL</td><td>Moxifloxacin ophthalmic solution 0.5% (administered twice daily)</td></tr>
<tr><td>Niva Thyroid tablet</td><td>NP Thyroid tablet</td><td>Potassium citrate/citric acid solution 1100-334 MG/5ML</td></tr>
<tr><td>Procentra solution 5 mg/5 mL*</td><td>Quillichew ER tablet</td><td>Renthyroid tablet</td></tr>
</table>

</td></tr>
</table>

	Roxybond tablet	Ryclora 2 mg/5mL oral solution	Sevelamer HCl tablet
	Thyroid tablet	Timolol hemihydrate 0.5% ophthalmic solution	Trandolapril/verapamil ER tablet
	Trospium chloride ER capsule 60 mg	Verapamil ER 24HR capsule	Zimhi prefilled syringe
	*Coverage of generic not impacted		

MEDICAL BENEFIT

Effective 01/01/2027
The following changes are being made to the listed medications and classes on the medical benefit:

<table>
<tr>
<td>IV Iron</td>
<td>

Effective 1/1/2027, the following IV iron agents will be covered with post service claim edits (PSCE) and will be preferred:

Venofer (J1756)
Infed (J1750)
Ferrlecit (J2916)

The following table outlines the PSCE parameters for the preferred IV iron products:

<table>
<tr><th>Drug and Code</th><th>Dose</th><th>ICD-10 Codes</th></tr>
<tr><td>Venofer (J1756)</td><td>• Administer Venofer 200 mg. Administer on 5 different occasions over a 14 day period.
• Max dose would be 1000 mg over 14 days. 1000 billable units per 14 days.</td><td rowspan="3">• All three drugs will have the following ICD-10 codes:
○ D50.0 Iron deficiency anemia secondary to blood loss (chronic)
○ D50.1 Sideropenic dysphagia
○ D50.8 Other iron deficiency anemias
○ D50.9 Iron deficiency anemia, unspecified
○ D63.0 Anemia in neoplastic disease
○ D63.1 Anemia in chronic kidney disease
○ D63.8 Anemia in other chronic disease classified elsewhere
○ D64.81 Anemia due to antineoplastic chemotherapy
○ Z51.11 Encounter for antineoplastic chemotherapy
○ Z51.89 Encounter for other specified aftercare</td></tr>
<tr><td>Infed (J1750)</td><td>• Dosing: The maximum daily dose of INFeD should not exceed 50mg/2mL.
• 1 billable unit per day is the maximum dose</td></tr>
<tr><td>Ferrlecit (J2916)</td><td>• 10 billable units per day is the maximum dose</td></tr>
</table>

Effective 1/1/2027, brand and generic formulations of the following IV iron product and HCPCS code will have prior authorization restrictions added and will be nonpreferred:

Feraheme (Q0138) (non-ESRD)

</td>
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</table>

	• Brand and generic formulations of the following products will continue to require prior authorization and will also be nonpreferred:
	  ○ Injectafer (J1439)
	  ○ Monoferric (J1437)
	• Initial and reauthorization criteria for Ferahema, Injectafer, and Monoferric will include a required trial and failure with one of the preferred IV iron products (Venofer, Infed, or Ferrlecit).
	• Members with active authorizations for brand and generic Injectafer and Monoferric for the HCPCS codes listed above will require a new authorization to continue coverage of their current agent on or after 1/1/2027.
	• Members currently being treated with brand and generic Feraheme (Q0138) will require an authorization to continue coverage with Feraheme on or after 1/1/2027.
	• The following additional criteria updates are being made to the Injectafer policy:
	  ○ Adding universal criteria to check serum phosphate levels at baseline and as clinically indicated AND to correct any pre-existing hypophosphatemia prior to administering treatment based on the new Boxed Warning added to the PI.
	  ○ Adding specific examples to the criteria for FDA labeled contraindications to provide better clarity and to more closely align with the PI.
	  ○ To Appendix A, updating the Safety and efficacy factor in the table to 'Yes: Consider for PA' to reflect the addition of the Boxed Warning to the PI.
	• To review the criteria in full for Injectafer, Feraheme and Monoferric, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Bendamustine	• All bendamustine products will continue to require prior authorization. • Effective 1/1/2027, Treanda will be the preferred bendamustine product. • Initial criteria for Bendeka, Belrapzo, bendamustine, and Vivimusta are being updated to include a required trial and failure with Treanda. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Ranibizumab	• All ranibizumab products will continue to require prior authorization. • Cimerli will continue to be a preferred ranibizumab product. • Effective 1/1/2027, Byooviz will be nonpreferred. Initial criteria for nonpreferred ranibizumab products (including Byooviz) will include a required trial and failure with a bevacizumab product and Cimerli. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Aflibercept Beovu Susvimo Vabysmo	• Updating initial criteria for aflibercept products, Beovu, Susvimo and Vabysmo to include a required trial and failure with a bevacizumab product and Cimerli; Byooviz is being removed as a previous trial option. • To review the criteria for these agents in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Bevacizumab Oncology	• All bevacizumab oncology agents will continue to be restricted with prior authorization. • Mvasi will continue to be a preferred bevacizumab oncology agent. • Effective 1/1/2027, Vegzelma will also be a preferred bevacizumab oncology agent. • Initial and reauthorization criteria for nonpreferred agents (Avastin, Alymsys, Avizi, Jobevne, Zirabev) will be updated to include a required trial and failure with Mvasi AND Vegzelma • Members currently on a nonpreferred agent (Avastin, Alymsys, Avizi, Jobevne, Zirabev) will need to demonstrate a trial and failure with both Mvasi and Vegzelma on reauthorization. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Denosumab	• All denosumab products will continue to require prior authorization. • Enoby, Stoboclo, Osenvelt and Xtrenbo will continue to be preferred denosumab products. • Jubbonti and Wyost will be moved to nonpreferred status. • Prolia, Xgeva, and all other denosumab biosimilars will remain nonpreferred. • Initial and reauthorization criteria for Prolia and nonpreferred biosimilars (including Jubbonti) will be updated to include a required trial and failure with Enboy AND Stoboclo. • Initial and reauthorization criteria for Xgeva and nonpreferred biosimilars (including Wyost) will be updated to include a required trial and failure with Osenvelt AND Xtrenbo. • Members currently utilizing Jubbonti or Wyost will require a new authorization to continue coverage of their current agent on or after 1/1/2027. Members on Jubbonti will not require a new authorization for Enoby or Stoboclo for the remainder of their existing authorization. Members on Wyost will not require a new authorization for Osenvelt or Xtrenbo for the remainder of their existing authorization. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Docetaxel	• Effective 1/1/2027, Beizray and Docivyx will require prior authorization. • Members currently being treated with Beizray or Docivyx will require prior authorization to continue coverage on or after 1/1/2027. • Criteria will require that an alternative docetaxel product (Taxotere [J9171) and docetaxel [Hospira] [J9232]), in any dosage strength, is not obtainable as confirmed by the FDA Drug shortage website. Beizray may bypass this trial requirement if the member has a polysorbate 80 hypersensitivity. • Additional diagnosis-specific criteria will also apply.

	• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Eculizumab	• All eculizumab products will continue to require prior authorization. • Effective 1/1/2027, Epysqli will be the preferred eculizumab product. Soliris and Bkemv will be nonpreferred. • Initial and reauthorization criteria for Soliris and Bkemv will include a required trial and failure with Epysqli. • Members currently being treated with Soliris or Bkemv will require a new authorization to continue coverage for their current agent on or after 1/1/2027. Members on Soliris or Bkemv will not require a new authorization for Epysqli for the remainder of their existing authorization. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
PiaSky	• Initial criteria are being updated to include a required trial and failure with either Epysqli or Ultomiris. This update will apply to members initiating treatment with PiaSky. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Izervay	• Initial criteria are being updated to include a required trial and failure with Syfovre. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Rituximab IV, Rituxan Hycela	• All rituximab products will continue to require prior authorization.
	• Truxima will continue to be a preferred rituximab product.
	• Effective 1/1/2027, Ruxience will also be a preferred rituximab product.
	• Initial and reauthorization criteria for nonpreferred rituximab products (Rituxan, Rituxan Hycela, Riabni) will be updated to include a required trial and failure with Truxima AND Ruxience.
	• Members currently on Rituxan, Rituxan Hycela, or Riabni will need to demonstrate trial and failure with both Ruxience AND Truxima on reauthorization.
	• The following additional criteria updates are being to the Rituximab IV policy:
	  ○ To SLE and LN, removing exclusion of use for severe active CNS lupus.
	  ○ To Appendix 1, removing ICD-10 codes C83.50-C83.58 (related to ALL) as it's no longer supported in NCCN. Adding ICD-10 codes E85.3, E85.4, E85.81, E85.89, E85.9 (related to Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma), T86.01, and T86.02 (related to Hematopoietic Cell Transplantation).
	• To review the criteria for Rituximab IV and Rituxan Hycela in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Tocilizumab IV Products	• All tocilizumab products will continue to require prior authorization. • Tyenne will continue to be a preferred tocilizumab product. • Effective 1/1/2027, Avtozma will also be a preferred tocilizumab product. • Actemra and Tofidence will continue to be nonpreferred. • Initial and reauthorization criteria for Actemra and Tofidence will be updated to include a required trial and failure with Avtozma AND Tyenne.

	• Members with active authorizations for Actemra or Tofidence will require a new authorization to continue coverage of their current agent on or after 1/1/2027. They will not require a new prior authorization for Tyenne or Avtozma for the remainder of the duration of their existing authorization. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Trastuzumab IV, Herceptin Hylecta	• Effective 1/1/2027, Kanjinti and Ontruzant will be nonpreferred and will require prior authorization. • Ogivri will continue to be preferred and covered without prior authorization. • Trazimera will be moved to preferred status and will be covered without prior authorization. • Members on Kanjinti or Ogiviri will require prior authorization to continue coverage on or after 1/1/2027. • Initial and reauthorization criteria for all nonpreferred trastuzumab products (Herceptin, Herceptin Hylecta, Kanjinti, Herzuma, Ontruzant, Hercessi) will be updated to include a required trial and failure with Ogivri AND Trazimera. Members currently on a nonpreferred trastuzumab product will need to meet this trial requirement on reauthorization. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Viscosupplements	• Effective 1/1/2027, Synvisc and Synvisc-One will be preferred and will be covered without prior authorization. • Durolane will continue to be a preferred viscosupplement and covered without prior authorization. • Visco-3 will be moved to nonpreferred status and will have prior authorization restrictions added. Members currently receiving treatment with Visco-3 will require prior authorization to continue coverage on or after 1/1/2027. • Initial and reauthorization criteria for all nonpreferred viscosupplements (including Visco-3) will be updated to include a required trial and failure with Durolane AND Synvisco/Synvisc-One. Members currently on a nonpreferred viscosupplement (including Visco-3) will need to meet this trial and failure requirement on reauthorization. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Berinert	• To universal criteria, updating exclusionary combination therapy statement to remove noted specific targets of treatment. Removing specific possible triggers for HAE attacks and replacing with statement confirming that the provider has counseled to avoid triggers for attacks. • Per updates in the 2025 World Allergy Organization guideline, Hereditary Angioedema with Normal C1 Inhibitor Updated International Consensus statement from HAE International (HAEi) and the US HAE Association (HAEA), and The International/Canadian Hereditary Angioedema 2026 Guideline the following was updated: To Treatment of Acute HAE Attacks, the indication heading was previously derived from PI and specified acute treatment being specifically allowed for abdominal, facial, or laryngeal attacks of HAE, however, this is being updated instead to “Treatment of acute attacks of Hereditary Angioedema (HAE)” based on latest guideline recommendations for use for all

	acute HAE attacks. Revising this section to align with current classification of disease, diagnosis, and treatment guidelines. • To renewal criteria, revising beneficial response criteria. • Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Cinryze	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To universal criteria, updating exclusionary combination therapy statement to remove noted specific targets of treatment and instead exclude any therapy indicated for the long term prophylaxis of HAE. Adding note allowing use in combination with other prophylactic therapies when Cinryze is used as short-term prophylaxis only. Removing specific possible triggers for HAE attacks and replacing with confirmation that the provider has counseled to avoid triggers for attacks. • Per updates in the 2025 World Allergy Organization guideline, Hereditary Angioedema with Normal C1 Inhibitor Updated International Consensus statement from HAE International (HAEi) and the US HAE Association (HAEA), and The International/Canadian Hereditary Angioedema 2026 Guideline, updating the following: To Prophylaxis for HAE Attacks indication, revising section to align with current classification of disease, diagnosis, and treatment guidelines. • To renewal criteria, revising beneficial response criteria. • Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Haegarda	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To universal criteria updating exclusionary combination therapy statement to remove noted specific targets of treatment and instead exclude any therapy indicated for the long term prophylaxis of HAE. Adding note allowing use in combination with Cinryze when used as short-term prophylaxis only. Removing specific possible triggers for HAE attacks and replacing with statement confirming that the provider has counseled to avoid triggers for attacks. • Per updates in the 2025 World Allergy Organization guideline, Hereditary Angioedema with Normal C1 Inhibitor Updated International Consensus statement from HAE International (HAEi) and the US HAE Association (HAEA), and The International/Canadian Hereditary Angioedema 2026 Guideline, updating the following: To Prophylaxis for HAE Attacks indication, revising section to align with current classification of disease, diagnosis, and treatment guidelines. • To renewal criteria, revising beneficial response criteria • Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.

	• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Ruconest	• To Universal criteria, removing specific contraindications in criteria and replacing with general language indicating member does not have any FDA contraindications and updating exclusionary combination therapy statement to remove noted specific targets of treatment. • Removing of specific possible triggers for HAE attacks and replacing with statement confirming that the provider has counseled to avoid triggers for attacks. • Per updates in the 2025 World Allergy Organization guideline, Hereditary Angioedema with Normal C1 Inhibitor Updated International Consensus statement from HAE International (HAEi) and the US HAE Association (HAEA), and The International/Canadian Hereditary Angioedema 2026 Guideline and KOL input the following was updated: To Treatment of Acute HAE Attacks indication, revising section to align with current classification of disease, diagnosis, and treatment guidelines. • To renewal criteria, revising beneficial response criteria. • Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
SCIG	• Removing HCPCS changes that would have been effective 01/01/2027 as per CMS these changes will no longer be made for 01/01/2027. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Takhzyro	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To universal criteria updating exclusionary combination therapy statement to remove noted specific targets of treatment and instead exclude any therapy indicated for the long-term prophylaxis of HAE, adding allowing use in combination with Cinryze when used as short-term prophylaxis only. • Removing specific possible triggers for HAE attacks and replacing with statement of confirmation that the provider has counseled to avoid triggers for attacks. • Per updates in the 2025 World Allergy Organization guideline, Hereditary Angioedema with Normal C1 Inhibitor Updated International Consensus statement from HAE International (HAEi) and the US HAE Association (HAEA), and The International/Canadian Hereditary Angioedema 2026 Guideline, updating the following: To Prophylaxis for HAE Attacks indication, revising section to align with current classification of disease, diagnosis, and treatment guidelines. • To renewal criteria, revising beneficial response criteria. • Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Adzynma	• Adding Universal Criteria to require that all members will have ADAMTS13 activity and ADAMTS13 neutralizing antibodies assessed prior to initiation and periodically during the course of treatment based on the new Boxed Warning in the PI. • Adding specific examples to the criteria for FDA labeled contraindications to provide better clarity and to more closely align with the PI. • Adding neutralizing antibodies to the examples of unacceptable toxicity in the Renewal Criteria section to align with the updates made to the PI. • To Appendix A, updating the Safety and efficacy factor in the table to 'Yes: Consider for PA' to reflect the addition of the Boxed Warning to the PI. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Amtagvi	• To Cutaneous Melanoma, removing footnote detailing alternate settings which could be considered as metastatic disease per changes in NCCN. • To Appendix 1, adding ICD-10 code C43.10 related to cutaneous melanoma. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Bavencio	• Removing ICD-10 crosswalk for PCM due to one single value in Max Units section. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Benlysta IV	• Removing SC formulation from policy. • Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include number of days allowed for authorization durations. • Updating dosing table to more clearly indicate age of pediatric members must be at least 5 years old and also updating the note regarding transition from IV to SQ use guidance, all per PI. • Updating reference section and removing quantity/dose requirements from initial/renewal criteria as this information was duplicative with the dosage/administration section. • Creating criteria blocks within the Initial criteria to separate Universal and Indication Specific Criteria for conciseness and to streamline the criteria review; condensing the concomitant immunomodulatory therapy criteria for conciseness while maintaining the same intent; streamlining language surrounding prerequisite and combination therapy; removing other FDA labeled or compendia supported diagnosis criteria and criteria noting 'medical records required' to shift to MPS standard procedures for review of those requests; streamlining renewal criteria to follow standard language formatting with reference to section III for all repeatable criteria required; removing steerage requirements. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Emrelis	• Updating Length of Authorization section to include the number of days allowed. • To Billing Code/Availability info, removing discontinued HCPCS codes C9306 and J9999.

	• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Fyarro	• Updating to Length of Authorization section to include days. • To Universal criteria removing specific contraindications in criteria and replacing with general language indicating member does not have any FDA contraindications. • To the Universal criteria, adding criteria for non-use in members with severe hepatic impairment per the updated PI. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Imfinzi	• To BTC, updating criteria on incidental findings on pathologic review for neoadjuvant therapy in gallbladder cancer to align with NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Imjudo	• No clinical changes being made to the criteria. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
IVIG	• Removing HCPCS changes that would have been effective 01/01/2027 as per CMS these changes will no longer be made for 01/01/2027. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Jemperli	• No clinical changes. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Kalbitor	• To universal criteria updating exclusionary combination therapy statement to removing noted specific targets of treatment. • Removing of specific possible triggers for HAE attacks and replacing with statement of confirmation that the provider has counseled to avoid triggers for attacks. • Per updates in the 2025 World Allergy Organization guideline, Hereditary Angioedema with Normal C1 Inhibitor Updated International Consensus statement from HAE International (HAEi) and the US HAE Association (HAEA), and The International/Canadian Hereditary Angioedema 2026 Guideline, updating the following: To Treatment of Acute HAE Attacks indication, revising section to align with current classification of disease, diagnosis, and treatment guidelines. • To renewal criteria, revising beneficial response criteria. • Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Libtayo	• No clinical changes. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Loqtorzi	• No clinical changes.

	• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Penpulimab	• To Head and Neck Cancers, updating footnote defining very advanced disease to align with NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Saphnelo IV	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include number of days allowed for authorization durations. • Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist to the policy. • Updating reference section, removing quantity/dose requirements from criteria within the initial/renewal for indication-specific criteria as this information was duplicative with the dosage/administration section. • Creating criteria blocks within the Initial criteria to separate Universal and Indication Specific Criteria for conciseness and to streamline the criteria review; condensing the concomitant immunomodulatory therapy criteria for conciseness while maintaining the same intent; aligning Indication Specific Criteria more closely with the Package insert while maintaining prerequisite and combination therapy intent; removing other FDA labeled or compendia supported diagnosis criteria; streamlining renewal criteria to follow standard language formatting with reference to section III for all repeatable criteria required; removing steerage requirements. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Tecentriq IV	• To NSCLC, updating criteria to align with NCCN compendia and guideline recommendations. • To Dosage/Administration table, combining rows for Colon Cancer and Small Bowel Adenocarcinoma for conciseness. • To Appendix 1 - Covered Diagnosis Codes, removing ICD-10 code Z85.51 as this is not supported in NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Tevimbra	• To both Gastric and Esophageal/Esophagogastric/Gastroesophageal Junction Cancers, adding newly approved FDA indication for use in combination with zanidatamab and fluoropyrimidine- and platinum containing chemotherapy as first line treatment of HER2- positive (IHC 3+ or IHC 2+/ISH+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma. • To Head and Neck Cancers, for Very Advanced disease removing duplicative treatment settings that fall under unresectable disease. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Tivdak	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Unloxcyt	• Updating Policy Name to reflect registered trademark. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Veopoz	• Updating Length of Authorization section to include the number of days allowed. • Removing any specific contraindications in criteria and replacing with general language indicating member does not have any FDA labeled contraindications. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Yartemlea	• To Billing Code/Availability section, removing obsolete J3590 HCPCS as it was discontinued on 07/01/2026. To Appendix 1, removing ICD-10 code M31.10 based on manufacturer billing guide. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Ziihera	• Add the FDA approved expanded indication for use in combination with fluoropyrimidine- and platinum-containing chemotherapy with or without tislelizumab for the first-line treatment of adults with HER2-positive unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma. • Updating Universal Criteria with criteria for monitoring and managing severe diarrhea as per black box warning update to the PI. • Updating Dosing Limits section, dosing table, and ICD-10 codes to reflect the addition of this new indication. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Zynyz	• No clinical changes. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates