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 10/01/2026
The following changes are being made to the listed medications and classes:

Benlysta	• Initial criteria for Benlysta are being updated to include diagnosis of either active lupus nephritis or systemic lupus erythematosus. Additionally, submission of medical records (e.g., chart notes) confirming member is positive for autoantibodies to SLE will be required. • Initial criteria are also being updated to restrict the prefilled syringe to members 18 years of age and older, which is aligned with the FDA-approved package labeling. The autoinjector and IV will be approved for members 5 years of age and older. • Initial criteria will require that either the member is receiving at least one standard of care treatment for the treated diagnosis or that all of the standard of care therapies are clinically inappropriate for the member.
Egrifta	• Updating initial criteria to include requirement of submission of medical records (e.g., chart notes) documenting minimum waist circumference requirements (female: > 88 cm; male: > 102 cm).

	• Updating reauthorization criteria to include requirement of submission of medical records (e.g., chart notes) documenting the member has had a decrease in waist size from baseline and that the member is currently receiving antiretroviral therapy.
Lupkynis	• In addition to requiring a diagnosis of active lupus nephritis and age of at least 18 years, initial criteria will require that either the requested medication is being used in combination with immunosuppressive therapy or that immunosuppressive therapy is clinically inappropriate for the member. Initial criteria will also require that the requested medication will not be used in combination with cyclophosphamide. • Reauthorization criteria will require that the member has achieved or maintained a positive clinical response as evidenced by lost disease activity or improvement in signs and symptoms of the condition
Nuzyra tablet	• Updating criteria to include requirement of inadequate response, intolerance, or contraindication to one first-line antibiotic indicated for the treated diagnosis. Examples include the following: amoxicillin, amoxicillin/clavulanate, ampicillin/sulbactam, azithromycin, cefotaxime, cefpodoxime, ceftriaxone, cefuroxime, clarithromycin, clindamycin, doxycycline, levofloxacin, linezolid, minocycline, moxifloxacin, sulfamethoxazole-trimethoprim, and vancomycin.
Spevigo SC	• Reauthorization criteria will be updated to require submission of medical records (e.g., chart notes) documenting an improvement in the member's condition, as evidenced by low disease activity or improvement in signs and symptoms of the condition.
Tocilizumab Products (Actemra, Avtozma, Tofidence, Tyenne)	• Initial criteria for systemic sclerosis-associated interstitial lung disease (SSc-ILD) will be updated to specify that only the subcutaneous formulation will be approved for the diagnosis.

MEDICAL BENEFIT

Effective 09/01/2026
The following changes are being made to the listed medications and classes:

Short-Acting GCSF	• Adding the new approved biosimilar product, Filkri. It will be kept at full parity with the reference product, Neupogen, and will require trial and failure with Zarxio in both the initial and renewal criteria. . • Updating the Max Units in the Dosing Limits section to reflect the addition of Filkri. • Updating Length of Authorization section to include the number of days for approval. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Effective 10/01/2026
The following changes are being made to the listed medications and classes:

Arcalyst	• Updating Appendix 1 to add ICD-10 code M04.3 and to note that M04.8 will be discontinued on 10/1/26. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Fasenra	• Updating to add the newly approved FDA expanded indication for the treatment HES without an identifiable non-hematologic secondary cause. Also adding dosing, dosing limits, and ICD-10 codes (D72.110, D72.111 and D72.119) for new HES indication. • To the severe eosinophilic asthma criteria, updating wording of exacerbation requirements to define each type of exacerbation and to clarify the number of exacerbations required • Adding agents to the Contraindicated as Concomitant Therapy table • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Nucala	• To the severe eosinophilic asthma criteria, updating wording of exacerbation requirements to define each type of exacerbation and to clarify the number of exacerbations required. • To COPD criteria, adding examples of COPD inhaled maintenance therapy and updating wording of exacerbation requirements to define each type of exacerbation and clarify the number of exacerbations required. • To HES criteria: updating diagnostic criteria measures; updating example listings of hypereosinophilia-related organ involvement and examples of non-hematologic secondary causes of HES; updating flare history criteria; updating HES conventional step therapy requirements; removing HES combo therapy requirements from Renewal criteria section. • Adding agents to the Contraindicated as Concomitant Therapy table. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Tezspire	• To the severe asthma criteria, updating wording of exacerbation requirements to define each type of exacerbation and to clarify the number of exacerbations required. • Adding agents to the Contraindicated as Concomitant Therapy table. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Vyvgart Hytrulo	• Updating to include the treatment of gMG in adults who are anti-acetylcholine receptor antibody (AChR-Ab) seronegative based on the expanded FDA approval. Previously use was only approved for adults who were AChR antibody positive and use is now allowed in all adults with gMG irrespective of AChR antibody status. • Updating the footnote in the dosing table to state, 'Administer subsequent treatment cycles based on clinical evaluation, but no sooner than 7 days from the last administration of the previous treatment cycle,' based on updated

	information provided in the Clinical Trials Experience section of the prescribing information. Updating the Max Units within the Dosing Limits section to reflect this change. • Updating Length of Authorization section to include the number of days for approval. • To the Renewal Criteria section, clarifying that non-use in combination with Rystiggo, Soliris, Bkemv, Epysqli, Ultomiris, Zilbrysq, or Imaavy only applies to gMG. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Xolair	• To the moderate to severe persistent asthma criteria, updating wording of exacerbation requirements to better define each type of exacerbation and to clarify the number of exacerbations required. • To the CSU criteria, removing "otherwise known as chronic idiopathic urticaria" and "CIU" acronym throughout. • Adding agents to the Contraindicated as Concomitant Therapy table. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Amvuttra	• 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 Universal Criteria updating examples of drugs not allowed in combination. • To renewal criteria updating nomenclature for Cardiomyopathy to include Hereditary to match the rest of the policy. • To Dosing table updating induction to “All Indications” for conciseness. • To Appendix 1 adding E85.4 for Organ-limited amyloidosis (related to ATTR-CM) per IPD. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Aveed	• Updating Length of Authorization section to include number of days allowed. • To Initial Approval criteria, updating verbiage in the bullet point precluding use in members with contraindications for the requested agent. • To Primary or Secondary Hypogonadism, removing bio-adhesive buccal testosterone as an example of topical testosterone agents as this product is no longer available on the market. • To the Dosing Table, adding additional dosing option of 750 mg at weeks 0, 4 and every 10 weeks thereafter for the treatment of gender dysphoria. • To Appendix 1, updating ICD-10 code F64.9 to note discontinuation on 10/1/26 and adding F64.A effective 10/1/26 along with its corresponding code description. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Bavencio	• No clinical changes. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Botox	• Updating Length of Authorization section to include number of days allowed for authorization durations. • Removing specific contraindications in criteria and replacing with general language indicating member does not have any FDA labeled contraindications. • To Prophylaxis for Chronic Migraines, clarifiying headache features that are consistent with migraines. • To Temporomandibular disorders, removing requirement of unilateral painful symptoms as per updated literature Botox can be used bilaterally. Corresponding updates were made to Dosage/Administration table and Max Units. • To Dosage/Administration table, updating dosing for Chronic Anal Fissures from 'up to 25 units' to 'up to 100 units' per review of updated literature. • To Appendix 1 – Covered Diagnosis Codes, adding G24.8 (related to Dystonias). • To Appendix 2, replacing retired LCAs of A57474, A56472, A52848, and A56646 with updated LCAs A59809, A59726, A59707, and A59714, respectively. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Cinqair	• To the severe eosinophilic asthma criteria, updating wording of exacerbation requirements to better define each type of exacerbation and to clarify the number of exacerbations required. • Adding agents to the Contraindicated as Concomitant Therapy table. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Datroway	• Adding the expanded indication for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy. • To the Universal criteria pertaining to conducting an ophthalmic exam, updating the criteria to specify that visual acuity testing and slit lamp examination must be conducted every 3 cycles based on the updated prescribing information. • To the HER-2 negative expression table, updating language to align with NCCN updated verbiage by including ERBB2. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Daxxify	• Updating Length of Authorization section to include number of days allowed for authorization durations. • Removing specific contraindications in criteria and replace with general language indicating member does not have any FDA labeled contraindications. • To Appendix 2, replacing retired LCA of A52848 with updated LCA A59707 and added LCAs A59726, A59714, and A59809. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Denosumab	• To Prolia and biosimilars: Updating Universal Criteria to remove specific contraindications in criteria and replace with general language indicating member does not have any FDA contraindications. • To osteoporosis in Men and Women, adding symbol with note regarding members with very high risk to reflect additional guideline supported

	treatment settings where members are not subject to prior trial and failure requirements with bisphosphonates. • To Xgeva and biosimilars: Updating Universal Criteria to remove specific contraindications in criteria and replace with general language indicating member does not have any FDA contraindications. • To multiple myeloma, adding footnote to indicate may also be used in combination with primary myeloma therapy for POEMS, MIDD, MGRS based on NCCN. • Per update to NCCN, indication of Systemic Mastocytosis is now supported by NCCN for Prolia and biosimilar products and no longer supported for Xgeva; therefore, moving indication to Prolia review portion of policy; making corresponding updates to MU, Renewal Criteria, dosing table, and Appendix 1 codes to reflect this change. • To Appendix 1 – Covered Diagnosis Codes, adding C50.A0-C50.A2 (related to breast cancer) and Z85.46 (related to prostate cancer) to both Prolia and Xgeva per NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Evenity	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To Universal Criteria, removing specific contraindications in criteria and replacing with general language indicating member does not have any FDA contraindications. • To note regarding members with very high risk, updating to reflect additional guideline supported treatment settings where members are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab. • To NDCs, adding new product, of single use glass PFS with automatic needle guard. • 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
Exdensur	• Removing references to the single-dose prefilled autoinjector presentation and to retain only the single-dose prefilled syringe presentation per the latest FDA decision. • To the severe eosinophilic asthma criteria, updating wording of exacerbation requirements to better define each type of exacerbation and to clarify the number of exacerbations required. • Adding agents to the Contraindicated as Concomitant Therapy table. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Firmagon	• Updating Length of Authorization section to allow approval duration of 6 months initially with 6 month renewal to algin with other oncology policies. • Updating to include the number of days approved. • Updating patient to member & coverage to prior authorization validity. • 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
Golimumab IV	• Renaming the policy Golimumab to encompass both Simponi ARIA and biosimilars. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Imfinzi	• To NSCLC, adding option for use in the subsequent setting for ERBB2 (HER2) mutation positive tumors and updating criteria for recurrent, advanced or metastatic disease to align with NCCN compendia and guideline recommendations. • To Bladder Cancer, adding new FDA approved indication for use in combination with BCG therapy for treatment of non-muscle invasive bladder cancer (NMIBC) with relevant criteria per the prescribing information. Making corresponding change to the dosing table to incorporate dosing for NMIBC. Updating Length of Authorization and Max Units sections accordingly. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Imjudo	• To NSCLC, adding option for use in the subsequent setting for ERBB2 (HER2) mutation positive tumors and updated criteria for recurrent, advanced or metastatic disease to align with NCCN compendia and guideline recommendations. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Jemperli	• To Length of Authorization, updating verbiage pertaining to renewals for anal carcinoma for clarity. • To dMMR/MSI-H Tumors, updating setting of neoadjuvant treatment of gastric cancers to better align with NCCN. Also to dMMR/MSI-H tumors, updating setting of primary treatment of endometrial carcinoma to indicate use is for recurrent disease. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Krystexxa	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To Universal Criteria, removing any specific contraindications in criteria and replacing with general language indicating member does not have any FDA contraindications. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Leuprolide Depot	• Updating Length of Authorization Section to include number of days allowed. • To Breast and Ovarian Cancer, adding J1954 based on NCCN update now including code and corresponding product Lutrate Depot. • To Uterine Sarcoma, removing J9217 since NCCN no longer lists any products associated with J code and updating criteria to include stage II-IV and ER/PR+ disease as additional therapy following total hysterectomy based on NCCN update. • To Head and Neck Cancer, adding J1950 and J9003 and removing J1954 based on codes/brand products listed on NCCN codes.

	• To Gender Dysphoria adding all J codes to heading as criteria applies to all products based on requirement of GnRH policies to be compliant with state statues. Corresponding updates were made to the Dosing Table based on the previously noted criteria/dosing changes: moving Uterine Sarcoma to fall under 3.75mg monthly/11.25mg every 3 months dosing only, for Head & Neck Cancer, adding Lupron Depot (J1950) and Camcevi ETM (J9003) dosing while removing Lutrate Depot & Leuprolide Acetate Depot (J9154) dosing, and to Gender Dysphoria which currently had dosing for Lupron Depot and Fensolvi, adding dosing for all other products now that the indication applies to all products in policy as well as removing requirement to use in combination with transdermal estradiol for Lupron Depot only. • Making corresponding updates to the Max Units Section as well based on the previously noted: to J1950, adding Head and Neck Cancer, moving Uterine Sarcoma from 6 to 3 billable units every 84 days, moving Gender Dysphoria from 3 billable units every 84 days to 24 units every 168 days, to J1952, adding Gender Dysphoria, to J1954, adding Breast/Ovarian Cancer and Gender Dysphoria and removing Head & Neck Cancer, to J9217, removing Uterine Sarcoma and adding Gender Dysphoria with 12 billable units every 336 days, and to J9003, adding Head & Neck Cancer and Gender Dysphoria. • To Renewal Section, updating all absence of toxicity statements to align with current package inserts for products which includes adding severe cutaneous adverse reactions based on package insert updates. • To Billing Code Section, adding 505b2 designation to Fensolvi, Camcevi and Camcevi ETM based on initial FDA approval letters and adding new Camcevi ETM NDC 69448-0024-xx, removing its discontinued unclassified code J3490. • Corresponding updates were made to Appendix 1 (ICD-10 codes) based on criteria updates previously noted: to J1950 adding C06.9, C07, C08.0-1, C08.9, D37.031-2, D37.039 (related to Salivary Gland Tumors), C50.A0-2 (related to Inflammatory Breast Cancer), to J9217, adding C50.A0-2 (related to Inflammatory Breast Cancer), removing C54.0-3, C54.8-9, C55, Z85.42 (related to Uterine Sarcoma), adding D37.031-2, D37.039 (related to Salivary Gland Tumors), adding F64.0-2, F64.8-9, F64.A (related to Gender Dysphoria), separating out J1954 into its own table from J1952. To J1952, adding D37.031-2, D37.039 (related to Salivary Gland Tumors) and adding F64.0-2, F64.8-9, F64.A (related to Gender Dysphoria). To J1954, adding all codes related to Breast Cancer including new codes related to Inflammatory Breast Cancer, Ovarian Cancer, Prostate Cancer, and Gender Dysphoria, to J9003, adding C06.9, C07, C08.0-1, C08.9, D37.031-2, D37.039 (related to Salivary Gland Tumors), adding F64.0-2, F64.8-9, F64.A (related to Gender Dysphoria), and to all J codes, updating F64.9 to note discontinued 10/1/26 and F64.A effective 10/1/26 with corresponding code description based on ICD10 code update (related to Gender Dysphoria). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Levoleucovorin	• To Initial Criteria, removing Mantle Cell Lymphoma for use in combination with high-dose methotrexate and added Neuroendocrine Tumors of the

	Gastrointestinal Tract (Well-Differentiated Grade 1/2), Lung, and Thymus for use in combination with fluorouracil-based regimens as per NCCN. • To Covered Diagnosis table, removing the following ICD-10 codes C83.10, C83.11, C83.12, C83.13, C83.14, C83.15, C83.16, C83.17, C83.18 (related to Mantle Cell Lymphoma) and adding D37.3 (related to Appendiceal Adenocarcinoma) per NCCN. • 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	• To NSCLC, updating criteria to align with NCCN compendia and guideline recommendations. • To Dosage/Administration table, updating single agent use duration for anal carcinoma to align with NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Loqtorzi	• To Length of Authorization, adding table with maximum length of therapy, dose and dosing frequency to align with other policies in same class. • To Head and Neck Cancers, for Very Advanced disease removing duplicative treatment settings that fall under unresectable disease. • To Notes box, adding an additional note to possible scenarios when previous therapy with a programmed death (PD-1/PD-L1)-directed therapy could be allowable. • To Dosing Table, updating dose for Anal Carcinoma. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Myobloc	• Updating Length of Authorization section to include number of days allowed for authorization durations. • Removing specific contraindications in criteria and replacing with general language indicating member does not have any FDA labeled contraindications. • To Prophylaxis for Chronic Migraines, clarifying headache features that are consistent with migraines. • To Appendix 2, replacing retired LCAs of A57474, A56472, A52848, and A56646 with updated LCAs A59809, A59726, A59707, and A59714, respectively. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Onpattro	• Updating Length of Authorization section to include number of days allowed for authorization durations. • Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To Universal Criteria updating examples of drugs not allowed in combination. • To Dosing Table updating naming of indication to correspond to the rest of the policy. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Opdualag	• Updating Length of Authorization section to include number of days allowed for authorization durations.

	• Updating the footnote for metastatic disease to include oligometastatic disease and brain metastases per NCCN. • To Appendix 1 - Covered Diagnosis Codes, adding C43.10 (related to Cutaneous Melanoma). • Updating renewal section to align with prescribing information. Added 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
Palonosetron	• Updating Length of Authorization section to include number of days allowed. • To CINV in adults and pediatrics, removing repeat dosing in multi day emetogenic regimens preclusion based on NCCN guidelines allowing use up to every 2 days. Updating dosing table and Max Units accordingly. • Updating HEC, MEC, risk factors tables to align with current NCCN guidelines. • To Billing Code section, updating verbiage on 505(b)(2) products with current links to NDC Directory and FDA Orange Book. • 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
Penpulimab-kcqx	• To Head and Neck Cancers, for Very Advanced disease, updating treatment settings to unresectable disease with prior radiation therapy or recurrent/persistent disease with distant metastases. Also updating footnote verbiage. • Additionally, for Head and Neck Cancers, updating criteria and Dosage/Administration table to clarify combination therapy is for 18 weeks then Penpulimab is continued as a single agent for the remainder of the treatment window. • To Notes box, adding an additional note to possible scenarios when previous therapy with a programmed death (PD-1/PD-L1)-directed therapy could be allowable. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Qalsody	• Updating Length of Authorization section to include number of days allowed. • 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
Radicava IV	• Updating Length of Authorization section to include number of days allowed. • 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
Rituximab IV	• To Adult ALL, adding option for use in dose-adjusted EPOCH + TKI regimen for patients with PH+ disease. • To CNS Cancers, adding note regarding interchangeability of products for intrathecal or intraventricular administration.

	• To primary CNS lymphoma, relapsed or refractory, adding option to use Ibrutinib with lenalidomide. • To Appendix 1, adding ICD-10 code M05.A related to RA. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Supprelin LA	• Updating Length of Authorization section to include number of days allowed. • Removing Universal Criteria and hypersensitivity preclusion (contraindication) to remain consistent across all policies in class. • To Renewal Criteria, adding severe cutaneous adverse reactions to unacceptable toxicities per prescribing information update. • Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To Appendix 1, updating ICD-10 code F64.9 to note discontinuation on 10/1/26 and adding F64.A effective 10/1/26 along with its corresponding code description. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Sustol	• Updating Length of Authorization section to include number of days allowed. • To CINV, updating statement on repeat dosing to clarify intent is not to use more frequently than once a week. • Updating HEC, MEC, and risk factors tables to align with current NCCN guidelines. • 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
Tecentriq IV	• To NSCLC, expanding ERBB2 (HER2) mutation positive tumors from first-line only to first-line or subsequent therapy for single-agent use (PS 3) and non-squamous combination regimens (PS 0–2), per NCCN 2A recommendation. • Adding new indication for use as single agent adjuvant treatment for muscle invasive bladder cancer (MIBC) after cystectomy in patients who have circulating tumor DNA molecular residual disease (ctDNA MRD). • Updating Length of Authorization, Dosage/Administration, and ICD-10 coding sections 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
Tecentriq Hybreza	• Adding the expanded indication for use as single agent adjuvant treatment for muscle invasive bladder cancer (MIBC) after cystectomy in patients who have circulating tumor DNA molecular residual disease (ctDNA MRD). Updating Length of Authorization, Dosage/Administration, and ICD-10 coding sections 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
Tecvayli	• To Multiple Myeloma, adding combination therapy with daratumumab IV with corresponding update to the dosing table per NCCN. • To the dosing table, adding dosing for combination therapy with talquetamab per NCCN.

	• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Testopel	• Updating Length of Authorization section to include number of days allowed. • To Initial Approval criteria, updating verbiage in the bullet precluding use in members with contraindications for the requested agent. • To Primary or Secondary Hypogonadism, removing bio-adhesive buccal testosterone as an example of topical testosterone agents as this product is no longer available on the market. • To Billing Code/Availability, removing discontinued HCPCS codes S0189 and J3490. • To Appendix 2, adding CMS article A57615 (Noridian Healthcare Solutions, jurisdiction E, F). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Tevimbra	• No clinical changes. To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Triptodur	• Updating Length of Authorization section to include number of days allowed. • Removing Universal Criteria and hypersensitivity preclusion (contraindication) to remain consistent across all policies in class. • To Renewal Criteria, adding severe cutaneous adverse reactions to unacceptable toxicities per prescribing information update. • Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To Appendix 1, updating ICD-10 code F64.9 to note discontinuation on 10/1/26 and adding F64.A effective 10/1/26 along with its corresponding code description. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Tzield	• Adding expanded indication to delay the decline in endogenous insulin production in pediatric patients age 8 to 17 recently diagnosed with Stage 3 type 1 diabetes. Also updating the Length in Authorization, Dosing Limits, Renewal Criteria, dosing table, and ICD-10 codes to reflect the addition of this new indication for use. • For Stage 2 T1D, updating the criteria to reflect separate diagnostic criteria for patients ≥ 1 year of age to < 18 years of age and ≥ 18 years of age to < 45 years of age based on updates made to the prescribing information based on updated clinical trial information and limitations of use. • Moving criteria for confirmation that Stage 2 T1D diagnosis is of autoimmune origin from under the Universal Criteria heading to under the criteria for Stage 2 T1D and also updating the verbiage in this criteria to align with the updated prescribing information verbiage. • To the Universal Criteria, adding criteria confirming that the patient has no FDA labeled contraindications to align with new contraindications for use added to the prescribing information. Also adding criteria confirming that therapy will not be used as a disease modifying therapy in non-autoimmune dysglycemic conditions per the new limitations of use in the updated prescribing information.

	• Adding ICD-10 crosswalk (for PCM). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Unloxcyt	• To Notes box, adding a note to possible scenarios when previous therapy with a programmed death (PD-1/PD-L1)-directed therapy could be allowable. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Vyepti	• Adding criteria to clarify the specific headache features that are consistent with migraines. • To the Renewal Criteria, adding severe constipation as an example of unacceptable toxicity based on the updated prescribing information. • Updating the Length of Authorization section to include the number of days for approval. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Vyvgart IV	• Adding treatment of gMG in adults who are anti-acetylcholine receptor antibody (AChR-Ab) seronegative based on the expanded FDA approval. • Amending the footnote in the dosing table to state, 'Administer subsequent treatment cycles based on clinical evaluation, but no sooner than 7 days from the last administration of the previous treatment cycle,' based on updated information provided in the Clinical Trials Experience section of the prescribing information. • Updating the Max Units within the Dosing Limits section to reflect this change. • Updating the Length of Authorization section to include the number of days for approval as part of the global change being made across all policies. • Removing the quantity/dose requirements from initial/renewal criteria as this information was duplicative with the dosage/administration section. • 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