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 11/01/2026
The following changes are being made to the listed medications and classes:

Botox	• Initial and reauthorization criteria for the treatment of upper limb spasticity are being updated to require trial and failure with either Dysport or Xeomin • Initial and reauthorization criteria for upper limp spasticity and lower limb spasticity are being updated to include a dosing limit of 400 units every 3 months. • Reauthorization criteria for Botox for treatment of migraine are being updated to limit the dose to 200 mg every 3 months, which aligns with initial criteria dosing limits.
Cyanocobalamin Nasal Spray	• Criteria are being updated to require that the member is 18 years of age or older. • Additionally, the member will need to have one of the following diagnoses: pernicious anemia in remission following intramuscular B-12 therapy, to be used as maintenance therapy, with no nervous system involvement; treatment of dietary, drug-induced, or malabsorption-related vitamin B-12 deficiency not

	due to pernicious anemia; prevention of B-12 deficiency (member has higher B-12 requirements than normal). • Criteria will also require that either the member has had an inadequate response (after 30 days of therapy), adverse reaction, or contraindication to both oral and injectable B-12 preparations OR that medical necessity for the nasal formulation is required. • The same criteria will apply to initial and reauthorization requests.
Livtencity	• Reauthorization criteria are being updated to require positive response to therapy and submission of resistance testing (e.g., quantitative CMV viral load monitoring, genotypic resistance sequencing) showing the member has not developed resistance to Livtencity.
Omega-3 ethyl esters (generic Lovaza), icosapent ethyl (generic Vascepa)	• Adding reauthorization criteria requiring submission of medical records (e.g., chart notes) demonstrating the member has had a positive response to therapy (e.g., reduction in triglycerides).

MEDICAL BENEFIT

Effective 11/01/2026
The following changes are being made to the listed medications and classes:

ACTH	• Updating Length of Authorization section to include number of days allowed for authorization durations. • Updating contraindications to therapy and 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
Leqembi SQ	• Adding the newly approved starting dosage regimen for the SQ formulation of Leqembi. Updating Length of Authorization, Initial Criteria, footnotes in the Renewal Criteria section, and to the dosing table to reflect this new dosing option. • Updating the Renewal Criteria pertaining to the frequency of MRI monitoring to align with the updates made to the prescribing information. • Adding the newly approved 250 mg/1.25 mL single-dose prefilled autoinjector, which provides for the new SQ starting dosage regimen of 500 mg once every week. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
SCIG	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To PID, adding use as supportive care during treatment with etuvetidigene autotemcel for Wiskott-Aldrich syndrome with a corresponding update to Renewal Criteria confirming continued treatment is necessary in members without adequate immune recovery.

	• Adding use in the Management of CAR T-Cell and Lymphocyte Engager-Related Toxicities per NCCN 2A recommendation. Corresponding updates made to Max Units, Renewal Criteria, and Dosage/Administration sections. • Updating descriptor for J1569 in HCPCS Codes. • Updating HCPCS for Gammaked, Gamunex-C, Gammagard Liquid, and Gammagard Liquid ERC. J1583 will be effective on 01/01/2027 for Gammaked and Gamunex-C. J1586 will be effective on 01/01/2027 for Gammagard Liquid and Gammagard Liquid ERC. J1561 will be discontinued for Gammaked and Gamunex-C on 01/01/2027 and J1569 will be discontinued for Gammagard Liquid and Gammagard Liquid ERC on 01/01/2027. • Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. To Appendix 1 - Covered Diagnosis Codes, added T80.82XA, T80.82XS, T80.89XA, and T80.89XS (related to CAR T-Cell and Lymphocyte Engager-Related Toxicities). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Adcetris	• Updating Universal Criteria to include concomitant use with bleomycin due to pulmonary toxicity as an example of a contraindication to therapy for ease of review. • Updating the notes box of Pediatric Classic Hodgkin Lymphoma to include adequate response to less than 4 cycles of chemotherapy in those with relapse between 3 and 12 months as a highly favorable disease trait. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Amvuttra	• Updating to clarify that the member must have 'baseline' NYHA Class I or II heart failure OR Class III heart failure. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Cosela	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To Billing Code/Availability Information, updating NDC per updated package insert. • 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
Darzalex IV	• To renewal criteria, updating the list of unacceptable toxicities to include serious infection per the latest package insert. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Erbitux	• To CRC criteria, updating combination with encorafenib and fluorouracil-based chemotherapy to encorafenib and fluoropyrimidine-based chemotherapy to encompass combination with CapeOX and simplified criteria throughout per review of NCCN. • To NSCLC, updating criteria 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
Evkeeza	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To HoFH, adding LDLRAP1 and ARH as allowable alleles for DNA testing per 2026 ACC/AHA/Multisociety guideline on the Management of Dyslipidemia. • To untreated LDL level, updating to reflect allowance for confirmation when member has untreated LDL >400 mg/dL (previous recommendations required >500 mg/dL) per 2023 European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolemia. • Retaining treated LDL level criterion. • Adding bempedoic acid to the list of LDL lowering therapy examples which may be used in conjunction. • Updating prior treatment history requirements: consolidating 3-month trial and failure from two step to a single option and will now be approvable when member meets either 6 month trial and failure of lomitapide or a 3 month trial and failure of a 3 drug combination and also updating the LDL goals criterion based on latest guidelines. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
IVIG	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To Primary Immunodeficiency, updating to include use as supportive care during treatment with etuvetidigene autotemcel for Wiskott-Aldrich syndrome with a corresponding update to Renewal Criteria confirming continued treatment is necessary in members without adequate immune recovery. • To Dermatomyositis and Polymyositis, adding option to bypass double-step if disease remains severe, refractory, or has the potential to have serious sequelae with use of steroids plus immunosuppressants alone. • To Management of Immune Checkpoint Inhibitor-Related Toxicities, updating use in myositis to align with NCCN update. • To Management of CAR T-Cell-Related Toxicities, adding Lymphocyte Engager to heading, updating anti-CD19 and BCMA-targeted CAR T-cell therapy toxicities to include bilateral facial palsy, and adding use for hypogammaglobulinemia in B-Cell Lymphoma with use of BiTE therapy per NCCN updates. • Adding use in Histiocytic Neoplasms - Pediatric Langerhans Cell Histiocytosis per NCCN 2A recommendation. • Corresponding updates were made to MU, Renewal Criteria, and Dosage/Administration sections for the new indications. • Removing product reference use only table. • To Billing Code/Availability Information, updating HCPCS codes for all products, except Qivigy and Yimmugo, which will be effective 01/01/2027. Corresponding updates were made to the Dosing Limits section. • To Appendix 1 - Covered Diagnosis Codes, adding C96.0, C96.5, C96.6, C96.9, C96.Z (related to Langerhans-cell histiocytosis) and G92.00-G92.04, Z29.89 (related to CAR T-Cell and Lymphocyte Engager-Related Toxicities). • Updating Appendix 2 to remove the retired LCAs A54662 and A57194 as Jurisdictions E and F were combined under A54660 and A57194.

	• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Keytruda IV	• To Biliary Tract Cancers, removing use for jaundice as neoadjuvant therapy per NCCN guidelines. • To Urothelial Carcinoma, removing criteria requiring member is ineligible for cisplatin-containing chemotherapy due to new FDA approval which extends approval of this regimen in neoadjuvant and adjuvant settings from patients who are cisplatin-ineligible to now also include cisplatin-eligible patients with MIBC who are candidates for cystectomy. • Updating Length of Authorization and Dosage/Administration to reflect expanded indication and provide details regarding different dosing schedules for neoadjuvant/adjuvant use in cisplatin-eligible vs. cisplatin-ineligible patients. • Also to Urothelial Carcinoma, adding exclusion for recurrence of stage T3-4 disease or palpable inguinal lymph nodes for recurrent/metastatic primary carcinoma of the urethra based on NCCN guidelines. • Updating criteria for Triple Negative Breast Cancer based on NCCN updates for the new FDA approved indication for use in combination with sacituzumab govitecan-hziy, for the first-line treatment of adult patients with unresectable locally advanced or metastatic disease. Updating LOA and Dosage/Administration section to reflect the addition of this new regimen. • To Renal Cell Carcinoma, adding new FDA indication (along with incorporating NCCN support into criteria) for adjuvant treatment in combination with belzutifan in adults with renal cell carcinoma with a clear cell component (ccRCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. Also removing prior SBRT from criteria which is category 2B or 3 in guidelines and removing with or without sarcomatoid features for stage II disease as well as removing within 1 year of nephrectomy for relapsed or stage IV disease to better align with Welireg policy. • To NSCLC, adding NCCN 2B criteria on mediastinal lymph node recurrence with prior radiation therapy and excluding use in patients with locoregional recurrence or symptomatic local disease without evidence and disseminated disease based on guidelines. • To Ovarian, Fallopian Tube, and Primary Peritoneal Cancer, adding NCCN 2B exclusion for treatment of biochemical relapse per NCCN guidelines. • To SCLC, adding note on avoiding immune checkpoint inhibitor in transformed SCLC based on NCCN update • To Thyroid Carcinoma and TMB-H Cancer, reformatting criteria to better align with new NCCN recs now including gross residual disease in neck after thyroidectomy. • Adding new indication of Malignant Histiocytic Neoplasms per NCCN 2A recommendation and corresponding updates were made to the MU and Dosing Table sections. • To Dosing Table for Soft Tissue Sarcoma, adding option for 400 mg every 6 weeks for single agent [excluding adjuvant treatment] per NCCN Dosing Templates. Updating Max Units section accordingly to now group STS under ‘all under indications’.

	• To Appendix 1, adding the following ICD-10 codes C96.20, C96.29, C96.9, and C96.Z (related to Malignant Histiocytic Neoplasms). • Updating ICD-10 crosswalk (for PCM) list. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Keytruda SC	• To Urothelial Carcinoma, removing criteria requiring member is ineligible for cisplatin-containing chemotherapy due to new FDA approval which extends approval of this regimen in neoadjuvant and adjuvant settings from patients who are cisplatin-ineligible to now include cisplatin-eligible patients with MIBC, who are candidates for cystectomy. Updating Length of Authorization and Dosage/Administration to reflect expanded indication and provide details regarding different dosing schedules for neoadjuvant/adjuvant use in cisplatin-eligible vs. cisplatin-ineligible patients. • To Triple Negative Breast Cancer, changing the CPS score from CPS ≥1 to CPS ≥10. Updating criteria for Triple Negative Breast Cancer based on new FDA approved indication of use in combination with sacituzumab govitecan-hziy, for the first-line treatment of adult patients with unresectable locally advanced or metastatic disease. Updating Dosage/Administration section to reflect the addition of this new regimen. • To Renal Cell Carcinoma, adding new FDA indication for adjuvant treatment in combination with belzutifan in adults with renal cell carcinoma with a clear cell component (ccRCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. • To Appendix 1, updating to include the following ICD-10 codes C96.20, C96.29, C96.9, and C96.Z (related to Malignant Histiocytic Neoplasms). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Leqembi IV	• Updating to align the dosing in IV policy with that of the SQ policy based on the FDA approval of a new starting dosage regimen for the SQ formulation of Leqembi. Previously approved only as an IV starting dosage, with the option for transitioning to IV or SQ maintenance dosage after 18 months of treatment. Updating footnotes in the Renewal Criteria section and to the dosing table to reflect this new dosing option. • Updating the Renewal Criteria pertaining to the frequency of MRI monitoring to align with the updates made to the package insert. • Updating the existing HCPCS code description for J0174, "Injection, lecanemab-irmb, 1 mg" to instead read "Lecanemab-irmb, for intravenous injection, 1 mg" to clarify the difference between SQ and IV formulations. • 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
Leqvio	• To Hypercholesterolemia, updating criteria to reflect changes from the 2026 ACC/AHA/Multisociety Guidelines on the Management of Dyslipidemia including updates to clarify diagnosis of ASCVD and to remove ASCVD risk ranges and to allow use for any member with treated LDL-C ≥ 100 or ≥ 70 with subclinical atherosclerosis or additional ASCVD risk factors.

	• To HoFH, adding ARH as allowable allele for DNA testing per 2026 ACC/AHA/Multisociety guideline. • To untreated LDL level, updating to reflect allowance for confirmation when member has untreated LDL >400 mg/dL (previous recommendations required >500 mg/dL) per 2023 European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolemia. • Retaining treated LDL level criterion. • Adding Bempedoic acid to list of options of LDL therapies to use in combination. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Opdivo IV	• To Biliary Tract Cancers, removing use for jaundice as neoadjuvant therapy per NCCN guidelines. • To Urothelial Carcinoma (Bladder Cancer), adding exclusion of recurrence of stage T3-4 disease or palpable inguinal lymph nodes for primary carcinoma of the urethra per NCCN guidelines. • To Pediatric CHL, adding response to < 4 cycles of chemo to highly favorable member criteria for re-induction therapy as per NCCN update. • To RCC, adding use for relapsed or stage IV disease with non-clear cell histology in combination with ipilimumab which is now a 2A NCCN recommendation and updating recommendation for subsequent therapy in combination with cabozantinib to include without prior immune-oncology therapy. • To NSCLC, adding verbiage on mediastinal lymph node recurrence with prior radiation therapy and excluding use in patients with locoregional recurrence or symptomatic local disease without evidence and disseminated disease. • To SCLC, updating to include note on avoiding immune checkpoint inhibitor in transformed SCLC based on NCCN update. • To Thyroid Carcinoma, updating to include new NCCN 2A rec for use in combination with ipilimumab for oncocytic and anaplastic carcinoma. LOA, Max Units, and Dosing Table being updated accordingly. • To Ovarian, Fallopian Tube, Primary Peritoneal Cancer, updating to include 2B exclusion on immediate treatment of biochemical relapse based on NCCN guidelines. • Adding new indication of Malignant Histiocytic Neoplasms to criteria and updated Dosing Table and Max Units, accordingly. • To Appendix 1, adding C96.20, C96.29, C96.9, C96.Z (related to Malignant Histiocytic Neoplasms), and Z85.850 (related to Thyroid Carcinoma). Updated ICD-10 crosswalk (for PCM) list. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Padcev	• Updating to include the expanded FDA indication for use in combination with pembrolizumab as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, for the treatment of adults with MIBC (no longer a requirement to be cisplatin-ineligible for this setting). • Updating LOA and dosing table to reflect expanded indication and provide details regarding the different dosing schedules for neoadjuvant/adjuvant use in cisplatin-eligible vs. cisplatin-ineligible members. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates

Perjeta	• Updating breast cancer indication when used as first-line maintenance as part of combination therapy trastuzumab, endocrine therapy, with or without pertuzumab, and with or without palbociclib, to incorporate new FDA approved indication for Ibrance with existing NCCN supported indication. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Rybrevant IV	• To NSCLC, updating "exon 21 L858R mutation positive" verbiage to now say "L858R mutation" to align with NCCN verbiage. Adding option for subsequent therapy in combination with lazertinib for disease progression on carboplatin or cisplatin/osimertinib/pemetrexed for nonsquamous histology or progression on osimertinib for symptomatic systemic disease with multiple lesions. • To CNS Cancers, updating criteria for use in brain metastases from NSCLC and adding new NCCN recommended indication for leptomeningeal metastases from EGFR exon 19 deletion or L858R mutation positive NSCLC in combination with lazertinib. • To Appendix 1, updating to include ICD-10 code C79.32 (related to Leptomeningeal Metastases). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Rybrevant SQ	• Per NCCN to substitute Rybrevant SQ in place of Rybrevant IV; aligning with Rybrevant IV policy. • To NSCLC, updating "exon 21 L858R mutation positive" verbiage to now say "L858R mutation" to align with NCCN verbiage. • Updating criteria to align with NCCN and Rybrevant IV policy. • Adding new indication for use in CNS cancers arising from EGFR exon 19 or exon 21 L858R mutation positive NSCLC with pertinent criteria and dosing per NCCN. • To Appendix 1, adding ICD-10 codes C79.31 and C79.32 related to CNS Cancers. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Sarclisa IV	• Adding criteria stating that therapy will not be used concomitantly with subcutaneous isatuximab to align with the newly created Sarclisa Escena (SQ) policy. • To Renewal Criteria, adding anaphylactic reactions to the list of unacceptable toxicities to align with package insert update • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Spravato	• Updating Length of Authorization section to include number of days allowed for authorization durations. • Updating contraindications to therapy and adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • Removing CMS Articles A59249 (Novitas Solutions) and A59250 (First Coast) as these have now been retired as of 12/18/25. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Tevimbra	• Adding the newly approved 150 mg/15 mL single-dose vial product and making corresponding updates to the Max Units section.

	• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Trastuzumab IV	• Updating breast cancer indication when used as first-line maintenance as part of combination therapy trastuzumab, endocrine therapy, with or without pertuzumab, and with or without palbociclib, to incorporate new FDA approved indication for Ibrance with existing NCCN supported indication. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Trodelvy	• Adding the expanded indication for use in combination with pembrolizumab for the first-line treatment of adult patients with unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥10). • Adding the expanded indication for use as a single agent as first-line treatment of adult patients with unresectable or metastatic TNBC who are not candidates for PD-1 or PD-L1 inhibitor based therapy. • Expanding coverage for TNBC to include inflammatory breast cancer per NCCN. • To HR+ HER2 negative disease, consolidating treatment options to include both the package insert and NCCN. Updating the HER2-negative expression criteria table to align with current NCCN verbiage. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Vectibix	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To CRC, updating criteria to align with changes in NCCN Colon and Rectal guidelines. • Updating section heading to reflect new NCCN guideline for Appendiceal Neoplasms and Cancers. Including recurrent, progressive, metastatic peritoneal-only, and extraperitoneal disease throughout. Adding neoadjuvant therapy to BRAF V600 E disease. Adding additional treatment settings and regimens for KRAS/NRAS and BRAF V600E wild type disease. Removing footnote for MMR/MSI testing per NCCN updates. • Adding new indication of Small Bowel Adenocarcinoma with relevant criteria and dosing per NCCN. • Adding Appendix A-Non-Quantitative Treatment Limitations (NQTL) Factor Checklist to policy. • To Appendix 1 - Covered Diagnosis Codes, adding C17.0, C17.1, C17.2, C17.3, C17.8, C17.9, and Z85.068 (related to Small Bowel Adenocarcinoma) and D37.3 (related to Appendiceal Neoplasms and Cancers) per NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Yervoy	• To Max Units Section, adding Pericardial Mesothelioma, Tunica Vaginalis Testis Mesothelioma to align with Opdivo IV policy. • To Biliary Tract Cancers, removing use for jaundice as neoadjuvant therapy per NCCN guidelines. • To RCC, adding use for relapsed or stage IV disease with non-clear cell histology in combination with nivolumab. • To NSCLC, adding verbiage on mediastinal lymph node recurrence with prior radiation therapy and excluding use in patients with locoregional recurrence or

	symptomatic local disease without evidence and disseminated disease since NCCN guidelines list as 2B. • To SBA, adding note on allowing subsequent therapy if checkpoint inhibitor monotherapy was previously received to align with Opdivo IV policy and NCCN compendia. • To Ovarian, Fallopian Tube, Primary Peritoneal Cancer, adding 2B exclusion on immediate treatment of biochemical relapse based on NCCN guidelines. • To Thyroid Carcinoma, including new NCCN 2A recommendation for use in combination with nivolumab for oncocytic and anaplastic carcinoma. Updating LOA, Max Units, and Dosing Table accordingly. • To Appendix 1, adding C73 and Z85.850 (related to Thyroid Carcinoma). • Updating ICD-10 crosswalk (for PCM) list. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates