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

Effective 08/01/2026
The following changes are being made to the listed medications and classes:

MEDICAL BENEFIT

Cosentyx	• Updating to allow use for the treatment of ankylosing spondylitis in patients 12 years of age and older. Updating the renewal criteria section and dosing table 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
Long-Acting GCSF	• Adding Neulasta 4 mg/0.4 mL single-dose vial formulation. • 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. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Ustekinumab	• Adding the expanded indication for the treatment of pediatric patients 2 years and older with moderately to severely active Crohn's disease. Updating the Initial and Renewal Criteria sections along with the dosing table to reflect the addition of this new indication.

	• Updating Crohn's disease indication to add "Adult" throughout the policy to distinguish between Adult and Pediatric indications. • Adding indication for use as supportive therapy in combination with marnetegragene autotemcel (Kresladi™). Updating the Initial Criteria, Length of Authorization, Max Units, and dosing table to reflect the addition of this new indication. • Updating HCPCS for Starjemza. Q5164 will be effective on 07/01/2026. C9399 and J3590 will be discontinued on 07/01/2026. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Adcetris	• To Universal Criteria, removing preclusion for use in combination with bleomycin and replaced it with statement indicating the member must not have any FDA contraindications to the drug. • To Adult CHL, for primary treatment in combination with nivolumab or dacarbazine, updating criteria to allow use with or without involved-site radiation per NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Aflibercept	• Updating to include up to every 20-week dosing for the treatment of neovascular (wet) age- related macular degeneration (nAMD) and diabetic macular edema (DME) in patients who have one year of successful response based on visual and anatomic outcomes. • Coding updates made to CMS reference A52451 (jurisdiction 6, K). • Administrative change to update HCPCS for Eydenzelt. Q5170 will be effective on 07/01/2026. J3590 will be discontinued on 07/01/2026. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Amondys 45	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include the number of days for approval. • 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
Bortezomib	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods as well as include number of days allowed. • Removing any specific contraindications in criteria and replacing with general language indicating member does not have any FDA contraindications. • To Multiple Myeloma heading, adding footnote that MM regimens may also be used for POEMS, MIDD, MGRS based on NCCN. • To WM/LPL, adding to the criteria that dosing in combination with rituximab and dexamethasone may also be used with or without cyclophosphamide, per NCCN recommendations. • Removing Adult T-Cell Leukemia/Lymphoma indication and criteria as per NCCN T-Cell Lymphomas guideline update which removes bortezomib regimen.

	• To Pediatric ALL, updating criteria to include BCR::ABL1 nomenclature throughout, per NCCN. • To Kaposi Sarcoma, updating definition of advanced disease in the R/R setting and added new setting for use of KSHV-Associated Inflammatory Cytokine Syndrome with relevant criteria per NCCN. • To Pediatric Hodgkin Lymphoma, updating criteria for relapsed or refractory disease. • To Dosing Table and Dosing Limits sections, updating cycle length from 35 days to 21 days for MM/SLCA indications to be most encompassing of available dosing patterns based on literature/PI support. • To Billing Code section, updating NDC for Dr. Reddy's, adding NDC for Fresenius Kabi, and adding Fosun Pharma USA along with its NDCs to the Maia Pharmaceuticals row. • Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • To ICD-10 table, adding C90.11, C90.21, C90.31 (related to Multiple Myeloma), D89.89 and D89.9 (related to KSHV Inflammatory Cytokine Syndrome) and removed C91.50, C91.52 (related to T-Cell Leukemia/Lymphoma). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Briumvi	• Updating Length of Authorization section to include the number of days for approval as part of the global change being made across all policies. • Removing tables containing specific diagnostic criteria for RRMS, SPMS, and CIS in order to streamline and simplify the policy. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Darzalex IV	• To MM, adding footnote to Multiple Myeloma heading that regimens may also be used for POEMS, MIDD, MGRS based on NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Darzalex Faspro	• To Multiple Myeloma, adding footnote to Multiple Myeloma heading that regimens may also be used for POEMS, MIDD, MGRS based on NCCN. Also, to Multiple Myeloma, adding use in combination with teclistamab as an option for members who have had prior therapy with lenalidomide and a proteasome inhibitor, and adding use as a single agent in maintenance therapy for transplant eligible patients to align with NCCN guidelines. Making corresponding updates to the Length of Authorization section and the Dosage/Administration table. • To Systemic Light Chain Amyloidosis, updating overarching criteria for Mayo stage IIIb cardiac disease and adding use in combination with venetoclax for relapsed or refractory disease based on NCCN update. Making a corresponding update to Dosage/Administration table. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Denosumab	• Adding HCPCS code Q5167 for Enoby and Xtrenbo. J3590 will be discontinued for Enoby, and Xtrenbo.

	• Removing HCPCS J3590 for Aukelso, Bosaya, Bildyos, and Bilprevda as it was discontinued on 04.01.2026. • Updating Length of Authorization section to include the number of days for approval as part of the global change being made across all policies. • Coding updates made to CMS reference A52399 (jurisdiction 6, K). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Elrexfio	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To Multiple Myeloma per NCCN update, adding asterisk and statement noting allowable for use in the treatment of Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS), Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS). • 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
Elzonris	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods as well as 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
Enjaymo	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include number of days allowed. • Under Universal Criteria, updating vaccine language. • To Billing/Coding updating NDC per new manufacturer PI. • 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
Epkinly	• Updating the dosing table to remove the recommendation for 24-hour hospitalization following administration of the first full 48 mg dose on Cycle 1 Day 15 in patients with relapsed/refractory diffuse large-B cell lymphoma or high-grade B-cell lymphoma based on the updated PI. • Adding a footnote to the dosing table stating to assess whether hospitalization or outpatient monitoring is appropriate based on comorbidities or other situational factors for the first 48 mg dosage of Epkinly per the PI. • Updating Length of Authorization section to include the number of days for approval as part of the global change being made across all policies. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Erbitux	• To CRC, updating criteria to align with changes in NCCN Colon and Rectal guidelines.

	• Adding new indication of Small Bowel Adenocarcinoma with relevant criteria and dosing per NCCN. • To NSCLC, updated "exon 21 L858R positive" verbiage to now say "L858R mutation" to align with NCCN verbiage. • To Appendix 1 - Covered Diagnosis Codes, removing ICD-10 codes C00.0, C00.1 & C00.2 related to Head & Neck Cancers, and adding C17.0, C17.1, C17.2, C17.3, C17.8, C17.9, and Z85.068 related to Small Bowel Adenocarcinoma per NCCN. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Exondys 51	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include the number of days for approval. • 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
Injectafer	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods. • Removing any specific contraindications in criteria and replacing with general language indicating member does not have any FDA contraindications. • To Iron Deficiency Anemia in Non-Dialysis-Dependent Chronic Kidney Disease, re-aligning ferritin, TSAT, and hemoglobin criteria based on new KDIGO guidelines for 2026. • To Iron Deficiency Anemia in members intolerant to or who have had unsatisfactory response to oral iron, updating to all use for conditions where iron is unlikely to be absorbed due to AGA 2024 guidelines. Also, updating hemoglobin value to align with current WHO 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
Izervay	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods as well as include number of days allowed. • Removing any specific contraindications in criteria and replacing with general language indicating member does not have any FDA contraindications. • 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
Keytruda IV	• Per updates to NCCN, to initial criteria for Anal Carcinoma adding combination with paclitaxel and carboplatin, then continuing as a single agent for inguinal node recurrence or first line therapy of metastatic disease; corresponding updates made to dosing and Length of Authorization sections to reflect this addition.

	• To Biliary Tract Cancers, adding option to use carboplatin if ineligible for cisplatin, adding additional options for incidental finding on pathologic review, and adding allowance as neoadjuvant therapy for members that have jaundice. • To Urothelial Carcinoma, removing exclusion for recurrence of stage T3-4 disease or palpable inguinal lymph nodes, adding first-line use in recurrent primary carcinoma of the urethra, and adding use as adjuvant therapy for members who did not have platinum based neoadjuvant therapy and have pT3, pT4, or pN+ disease. • To Triple Negative Breast Cancer, adding use in combination with sacituzumab govitecan as first line therapy for recurrent unresectable or metastatic disease OR inflammatory disease. • To Cervical Cancer, adding option to continue pembrolizumab as maintenance therapy after combination with CRT for FIGO 2014 Stage III-IVA disease. • To Head and Neck Cancers, for Very Advanced disease removing duplicative treatment settings that fall under unresectable disease. • To Kaposi Sarcoma, removing exclusion for patients with multicentric Castleman disease (MCD) or KSHV–associated inflammatory cytokine syndrome (KICS) as this is up to provider discretion. • To Cutaneous Melanoma, for use in combination with lenvatinib removing requirement for disease progression following treatment with anti PD1/PDL1-based therapy, updating adjuvant treatment clinical settings, and updating footnote for metastatic disease. • To NSCLC as subsequent therapy for recurrent, advanced or metastatic disease, removing requirement for PD-L1 expressing tumors and added use for ERBB2 (HER2) positive disease. • To Ovarian Cancer, removing exclusion for treatment of biochemical relapse and added use for small cell carcinoma of the ovary, hypercalcemic type as a single agent for progressive or recurrent disease; corresponding update was made to dosing table to reflect this addition. • To Soft Tissue Sarcoma, adding new recommendation for use in combination with radiation therapy as neoadjuvant, followed by single agent adjuvant therapy with all corresponding criteria,; the dosing section and Length of Authorization sections were updated accordingly to reflect this addition. • To MSI-H/dMMR Cancers, adding use as neoadjuvant therapy for Small Bowel Adenocarcinoma and removing exclusion for Biliary tract cancers. • To TMB-H cancer, adding use as initial therapy for Small Bowel Adenocarcinoma when member has pMMR/MSS disease with previous FOLFOX/CAPEOX. • To ICD10 Table, adding C43.10 related to Cutaneous Melanoma, C50.A0, A1, and A2 related to inflammatory breast cancer, and D48.60-D48.62 related to STS - Borderline/Malignant Phyllodes Tumor of the Breast. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Keytruda QLEX	• To initial criteria for Esophageal cancer updating verbiage to align with PI. • To Dosing table for SCCHN aligning verbiage to PI dosing. • To Billing/Coding section, removing discontinued J9999

	• To ICD10 Table, adding C43.10 related to Cutaneous Melanoma, C50.A0, A1, and A2 related to inflammatory breast cancer, and D48.60-D48.62 related to STS - Borderline/Malignant Phyllodes Tumor of the Breast. To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Kyprolis	• 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. • To MM, added footnote to Multiple Myeloma heading that regimens may also be used for POEMS, MIDD, MGRS based on NCCN. • Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. • Adding ICD-10 codes C90.11, C90.21, and C90.31 (related to Multiple Myeloma). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Lemtrada	• 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 specific contraindications in the Universal Criteria and replacing with general language indicating member does not have any FDA labeled contraindications. • To the Universal Criteria, adding criteria requiring AST, ALT, alkaline phosphatase, and bilirubin levels to be measured at baseline and periodically throughout therapy based on the PI. • Moving the criteria for single agent use from under the Multiple Sclerosis heading to under the Universal Criteria heading as it needs to be confirmed upon each renewal. • Removing tables containing specific diagnostic criteria for RRMS and SPMS. • To the Renewal Criteria, updating the examples of unacceptable toxicity to more closely align with the Warnings and Precautions section of the PI. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Lynozyfic	• Updating Length of Authorization section to include number of days allowed for authorization durations. • To MM, adding footnote to Multiple Myeloma heading that regimens may also be used for POEMS, MIDD, MGRS based on NCCN. • Adding orphan drug designation for Multiple Myeloma. • To Billing Code/Availability section, adding HCPCS code J9601 and removing HCPCS codes C9307 and J9999 per IPD. • 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
Monoferric	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods. • Removing any specific contraindications in criteria and replace with general language indicating member does not have any FDA contraindications.

	• To Iron Deficiency Anemia in Non-Dialysis-Dependent Chronic Kidney Disease, re-aligning ferritin, TSAT, and hemoglobin criteria based on new KDIGO guidelines for 2026. • To Iron Deficiency Anemia in members intolerant to or who have had unsatisfactory response to oral iron, allowing use for conditions where iron is unlikely to be absorbed due to AGA 2024 guidelines. Also, updating hemoglobin value to align with current WHO 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
Natalizumab	• 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 tables containing specific diagnostic criteria for RRMS, SPMS, and CIS in order to streamline and simplify the policy. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates.
Ocrevus IV	• 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 specific contraindications in the general Initial Criteria replacing with general language in the Universal Criteria section indicating member does not have any FDA labeled contraindications. • Removing tables containing specific diagnostic criteria for RRMS, PPMS, SPMS, and CIS. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Ocrevus Zunovo	• Updating Length of Authorization section to include the number of days for approval as part of the global change being made across all policies. • Removing specific contraindications in the general Initial Criteria and replacing with general language in the Universal Criteria section indicating member does not have any FDA labeled contraindications. • Removing tables containing specific diagnostic criteria for RRMS, PPMS, SPMS, and CIS. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Opdivo IV	• To Ampullary Adenocarcinoma, adding ECOG status to combination with ipilimumab and added criteria for single agent use per NCCN updates. Making a corresponding update to Dosage/Administration section for single agent use and to MU. • To Anal Carcinoma, adding combination use with paclitaxel and carboplatin, then continuation as a single agent for inguinal node recurrence or first line treatment of metastatic disease. Making corresponding updates to the Length of Authorization and Dosage/Administration sections. • To Biliary Tract Cancers, adding use in T1b or greater and/or T1a with positive margins as findings on pathologic review for neoadjuvant use and added use as neoadjuvant therapy for gallbladder cancer with jaundice per NCCN updates.

	• To Urothelial Carcinoma (Bladder Cancer), removing exclusion of recurrence of stage T3-4 disease or palpable inguinal lymph nodes for primary carcinoma of the urethra per NCCN update. • To Adult CNS Cancers, updating criteria for use for brain metastases from melanoma and NSCLC. • To SCCHN very advanced disease, removing duplicative treatment settings that fall under unresectable disease. • To Adult CHL, updating description for use in combination with AVD per NCCN. • To Cutaneous Melanoma use as single agent adjuvant therapy, adding use in NED after initial treatment with local or regional therapy for clinical satellite/in-transit metastases AND local satellite/in-transit recurrence and removed the requirement of TLND for resectable disease limited to nodal recurrence following excision of recurrence per NCCN updates. Additionally, updating the footnote for metastatic disease to include oligometastatic disease and brain metastases per NCCN. • To NSCLC, adding use as subsequent therapy for disease positive for ERBB2 (HER2) per NCCN update. • To Small Bowel Adenocarcinoma, adding option for combination use with ipilimumab as subsequent therapy for advanced or metastatic disease if checkpoint inhibitor monotherapy was previously received. • To Soft Tissue Sarcoma, adding use as subsequent therapy for unresectable or metastatic TMB-H Borderline/Malignant Phyllodes Tumor of the Breast per NCCN. • Adding indication of Ovarian, Fallopian Tube, and Primary Peritoneal Cancer - clear cell carcinoma of the ovary and small cell carcinoma of the ovary (hypercalcemic type) with corresponding updates made to LOA, MU, and Dosing/Administration sections per NCCN 2A recommendation. • To Dosage/Administration section, adding an additional dosing option for CRC, Appendiceal Neoplasms and Cancers, and Small Bowel Adenocarcinoma per NCCN. Additionally, updating age and weight for Pediatric cHL to reflect new FDA-approval for this indication. • To Appendix 1 - Covered Diagnosis Codes, adding C43.10 (related to Cutaneous Melanoma), C56.1-C56.3, C56.9, C57.00-C57.02, C57.10-C57.12, C57.20-C57.22, C57.3, C57.4, C57.7-C57.9, Z85.43 (related to Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer), and D48.60-D48.62 (related to Soft Tissue Sarcoma). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Sarclisa	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include number of days allowed. • To MM, adding footnote to Multiple Myeloma heading that regimens may also be used for POEMS, MIDD, MGRS based on NCCN. Also to MM, adding option for use as primary treatment in combination with lenalidomide and dexamethasone for non-transplant candidates or if transplant is deferred. Dosing table was updated to include this new regimen.

	• To the dosing table, updating dosing regimen for combination therapy with carfilzomib, lenalidomide and dexamethasone in transplant candidates to allow up to 8 induction cycles (previously only 6 induction cycles) per changes in NCCN. Length of authorization was updated to reflect this change. • 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
Scenesse	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods as well as 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
Spinraza	• Adding the new high dose regimen along with the new 28 mg/5 mL and 50 mg/5 mL single dose vial formulations. • Updating renewal criteria to include criteria for transitioning to the high dose regimen. • Updating Max Units to align with dosing table. • From Appendix 2, removing CMS Article A58578 (jurisdiction E and F) as it was retired on 01.02.2025. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates.
Talvey	• 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. • To Initial Criteria, updating to include use in patients who are scheduled for and awaiting to receive step up doses. • To Multiple Myeloma, adding footnote to Multiple Myeloma heading that regimens may also be used for POEMS, MIDD, MGRS based on NCCN. Also, to Multiple Myeloma, adding use as bridging option for BCMA CAR-T therapy in relapse and/or refractory myeloma per NCCN 2A recommendation. • 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
Tecvayli	• 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. • To Initial Criteria, updating to include use in patients who are scheduled for and awaiting to receive step up doses. • To Multiple Myeloma, adding footnote to Multiple Myeloma heading that regimens may also be used for POEMS, MIDD, MGRS based on NCCN. Also, to Multiple Myeloma, updating to allow use in combination with daratumumab per NCCN update. Making corresponding update to Dosage/Administration table.

	• 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
Tzield	• Updating to expand the indication for use to delay the onset of Stage 3 type 1 diabetes (T1D) to pediatric patients between 1 to 8 years of age with Stage 2 T1D. • Updating the criteria for absence of active EBV or CMV to now also include criteria for confirmation of an undetectable viral load per the updated PI. \ • Updating the criteria for non-use in patients with Type 2 DM to now state that it will be confirmed that diagnosis is of autoimmune origin and does not suggest Type 2 Diabetes Mellitus or other forms of diabetes per the updated PI. • Updating the dosing table to reflect use in this new patient population. • Updating the Non-Quantitative Treatment Limitations (NQTL) Factor Checklist table in Appendix A to change the Safety and efficacy factor from 'No: PA not a priority' to 'Yes: Consider for PA' as a Boxed Warning has now been added to the PI. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Vabysmo	• Removing the 6-month duration specified for monthly dosing for the treatment of macular edema following retinal vein occlusion (RVO) based on the updated PI. Updating the Length of Authorization, Dosing Limits, Renewal Criteria, and dosing table to reflect this change. • Updating Length of Authorization section to include the number of days for approval as part of the global change being made across all policies. • Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist to the policy as a part of the global changes being made across all policies. • Updating Initial and Renewal Criteria sections to update 'coverage' to 'prior authorization validity'. Coding updates made to CMS reference A52451 (jurisdiction 6, K). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Viltepso	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include the number of days for approval. • 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
Vyondys53	• Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include the number of days for approval. • 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
Yervoy	• To Ampullary Adenocarcinoma, adding ECOG status to criteria per NCCN. • To Biliary Tract Cancers, adding use in T1b or greater and/or T1a with positive margins as findings on pathologic review for neoadjuvant use and added use as neoadjuvant therapy for gallbladder cancer with jaundice per NCCN updates. • To CNS Cancer, updating criteria for use for brain metastases from melanoma. • To Cutaneous Melanoma use as single agent adjuvant therapy, adding use in NED after initial treatment with local or regional therapy for local satellite/in-transit recurrence and removed the requirement of TLND for resectable disease limited to nodal recurrence following excision of recurrence per NCCN updates. Additionally, updating the footnote for metastatic disease to include oligometastatic disease and brain metastases per NCCN. • To NSCLC, adding use as subsequent therapy of disease positive for ERBB2 (HER2) per NCCN update. • To Soft Tissue Sarcoma, adding use as subsequent therapy for unresectable or metastatic TMB-H Borderline/Malignant Phyllodes Tumor of the Breast per NCCN. • Adding indication of Ovarian, Fallopian Tube, and Primary Peritoneal Cancer - clear cell carcinoma of the ovary and small cell carcinoma of the ovary (hypercalcemic type) with corresponding updates made to LOA, MU, and Dosing/Administration sections per NCCN 2A recommendation. • To Appendix 1 - Covered Diagnosis Codes, adding C43.10 (related to Cutaneous Melanoma), C56.1, C56.2, C56.3, C56.9, C57.00-C57.02, C57.10-C57.12, C57.20-C57.22, C57.3, C57.4, C57.7-C57.9, Z85.43 (related to Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer), and D48.60-D48.62 (related to Soft Tissue Sarcoma). • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates
Zynyz	• Adding new dosing regimen of 375 mg every 3 weeks for squamous cell carcinoma of the anal canal (SCAC) when used as monotherapy or combination therapy. • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates