# Formulary Updates

## DEFINITIONS

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

**MEDICAL BENEFIT**

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| Bevacizumab - Oncology | • To adult CNS cancer, adding use as a single agent for progressive or symptomatic Neurofibromatosis type 2–related schwannomatosis.<br>• To colorectal cancer, clarifying that combination with trifluridine/tipiracil may be used after oxaliplatin- and irinotecan-based therapy or beyond second line treatment, based on NCCN guideline update.<br>• To NSCLC, **a**dding ERBB2 (HER2) mutation–positive tumors to the list of actionable biomarker in the subsequent line of therapy setting based on NCCN updates.<br>• To ovarian cancer, adding use with paclitaxel for recurrent/progressive small cell carcinoma (hypercalcemic type).<br>• Updating criteria for epithelial, ovarian, fallopian tube, or primary peritoneal type for use in combination with paclitaxel and pembrolizumab for PD-L1–positive disease to include persistent/recurrent disease without restriction to prior lines of therapy.<br>• Adding additional NDC listings for Alymsys products. |

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| | • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Bizengri | • Updating the Length of Authorization section to delineate between authorization durations for initial and renewal periods as well as include number of days allowed.<br>• To NSCLC, adding use for unresectable disease to more closely align with PI.<br>• Adding new indication to all applicable sections of the policy for Biliary Tract Cancers (Intra/Extra-hepatic Cholangiocarcinoma), based on NCCN recommendations and FDA approval for use in adults with advanced unresectable or metastatic cholangiocarcinoma harboring a NRG1 gene fusion with disease progression on or after prior systemic therapy.<br>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.<br>• Adding codes: C22.1, C24.0, C 24.8 and C24.9 (all related to Biliary Tract Cancers) as covered diagnosis codes.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Crysvita | • Updating the Length of Authorization section to include the number of days for approval.<br>• Removing criteria requiring Crysvita to be prescribed by, or in consultation with, a nephrologist or endocrinologist.<br>• Adding Universal Criteria for members at high risk for hypercalcemia to have serum calcium and parathyroid hormone levels assessed prior to starting and during therapy.<br>• Adding moderate to severe hypercalcemia as an example of unacceptable toxicity per the Warnings and Precautions section to the Renewal section.<br>• To the dosing table, adding an optional dose increase regimen for adult patients with XLH who have an inadequate response to the currently approved 1.0 mg/kg every four weeks dosing regimen based on the newly FDA approved dosing.<br>• Adding dosing criteria for adult and pediatric patients with XLH that have serum phosphorus is within the normal range.<br>• To the dosing table for TIO, adding criteria to assess fasting serum phosphorus level 2 weeks after dose adjustment and to refer to prescribing information for stepwise dose increase and decrease schedule.<br>• Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist to the policy.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Enhertu | • To Breast Cancer, updating recs for HER2+ disease to include recurrent disease as well as inflammatory breast cancer with no response to preoperative therapy as per NCCN.<br>• Adding two new FDA approved indications in adults with HER2-positive early-stage breast cancer. The first indication is for the neoadjuvant treatment of Stage II or III breast cancer, followed by taxane, trastuzumab, and pertuzumab |

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| | (THP). The second indication is for the treatment of adults who have residual invasive disease after neoadjuvant HER2-targeted treatment. Updating Dosing Table and LOA sections accordingly.<br>• To CNS Cancer, updating criteria to align with NCCN guidelines. Also adding HER-low disease and leptomeningeal metastases from breast cancer as per NCCN updates.<br>• To CRC, updating with current NCCN recs which allow use for progression of advanced or metastatic disease without designation of line of therapy.<br>• Updating Appendiceal Adenocarcinoma to Appendiceal Neoplasms and Cancers throughout policy and updating with current NCCN which includes removing footnote related to dMMR/MSI-H or POLE/POLD1 disease as it not longer applies to the rec.<br>• To Ampullary Adenocarcinoma, adding option for use in intermediate ECOG PS 2 as per NCCN.<br>• To Cervical Cancer, removing unresectable disease to align with NCCN.<br>• Updating recs for Occult Primary to align with latest NCCN 2A recs.<br>• To Pancreatic Adenocarcinoma, aligning recs with current NCCN recs to allow use as subsequent therapy for locally advanced/metastatic/recurrent disease and removing rec for alternative systemic therapy as this can now be reviewed under subsequent therapy heading.<br>• To Endometrial Carcinoma, removing unresectable and metastatic from subsequent therapy criteria leaving recurrent only to align with current NCCN rec. Also updating criteria to exclude use in certain clinical settings (for locoregional recurrence and surgical exploration for locoregional recurrence) categorized as 2B recommendations in NCCN guidelines.<br>• To Vulvar Cancer, removing unresectable disease to align with NCCN. To the HER2-positive overexpression criteria table, updating language to align with NCCN updated verbiage and separating out Endometrial Carcinoma under the Solid Tumors section.<br>• To the HER2-positive overexpression criteria table, updating language to align with NCCN updated verbiage and separating out Endometrial Carcinoma under the Solid Tumors section. Additionally, to HER2-negative expression criteria table, updating language to align with NCCN updated verbiage and adding CNS to the HER2-low expression criteria table<br>• To Appendix 1 (Covered Diagnosis Codes), adding C50.A0-A2 (related to Breast Cancer), C79.32 (related to CNS Cancer), D37.031, D37.032, D37.039 (related to Head and Neck Cancer) and D37.3 (related to Appendiceal Neoplasms and Cancers).<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Kadcyla | • 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.<br>• To Universal Criteria, adding unless otherwise specified to single agent therapy criteria based on new NCCN CNS rec allowing combination use.<br>• To Brest Cancer, adding clarification for local or regional unresectable disease per NCCN. |

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| | • To CNS cancers, adding use in combination with neratinib per NCCN and streamlining criteria.<br>• To HER2-positive overexpression criteria table, updating language to align with NCCN updated verbiage by including ERBB2 (also added to CNS criteria based on NCCN).<br>• Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist. To ICD10 Table, added C50.A0, A1, and A2 (related to inflammatory breast cancer) and D37.031, D37.032, D37.039 (related to Head and Neck Cancer - Salivary Gland Tumors).<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Margenza | • 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.<br>• Adding Appendix A-Non-Quantitative Treatment Limitations (NQTL) Factor Checklist to policy.<br>• Adding ICD-10 codes C50.A0-C50.A2 (related to Breast Cancer) per NCCN.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Ocrevus IV | • Adding the expanded indication for the treatment of relapsing-remitting multiple sclerosis in pediatric patients 10 years of age and older who weigh 25 kilograms or more.<br>• Adding specific examples in parentheses after the general criteria for no FDA labeled contraindications.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Paclitaxel Albumin-Bound | • To all oncology indications where it was not previously noted already, adding criteria for use as substitution for paclitaxel or docetaxel if the member has experienced hypersensitivity reactions despite premedication or member has contraindications to standard hypersensitivity premedication.<br>• To NSCLC, for use as subsequent therapy updating biomarker to ERBB2 (HER2) based on NCCN update.<br>• To Ovarian, Fallopian Tube and Primary Peritoneal Cancer, adding new rec for platinum-resistant persistent disease or recurrence in combination with relacorilant to all types of disease and updating Dosing Table accordingly.<br>• To Pancreatic Cancer, updating criteria to align with NCCN which include adding new regimen for use as a component of PAXG, use as alternate neoadjuvant therapy following progression, and updating criteria for use as subsequent therapy.<br>• For the new rec as a component of PAXG, updated Dosing Table and LOA accordingly.<br>• To Cutaneous Melanoma, adding symptomatic disease and eligibility criteria to align with updated NCCN verbiage.<br>• To BTC, adding additional incidental findings to criteria based on NCCN update.<br>• To Appendix 1 – Covered Diagnosis Codes, adding C43.10 (related to Cutaneous Melanoma). |

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| | • To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Pemetrexed | • To CNS Cancers, adding note regarding interchangeability of products for intrathecal administration per updates to NCCN.<br>• To Thyroid Cancer, adding option for use in locoregional invasive disease and unresectable gross residual disease after thyroidectomy for follicular, papillary and oncocytic carcinoma.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Perjeta | • To Breast Cancer, adding use as first-line maintenance therapy in combination with aromatase inhibitor and trastuzumab with or without palbociclib in members with hormone receptor-positive disease per NCCN update.<br>• To Central Nervous System (CNS) Cancers, reformatting criteria to align with NCCN and simplifying criteria for use for brain metastases from breast cancer.<br>• To Colorectal Cancer (CRC), allowing use as subsequent therapy in any disease setting per NCCN update.<br>• To Appendiceal Cancer, updating heading to reflect new NCCN naming convention for indication, which is being updated throughout policy.<br>• Adding indication of Small Bowel Adenocarcinoma per NCCN. Corresponding addition to HER2-positive overexpression criteria chart was made.<br>• To Dosage/Administration table, reformatting breast cancer to call out initial and maintenance dosing.<br>• Adding the following ICD-10 codes per NCCN: C17.0-C17.3, C17.8, and C17.9. Z85.068 (related to Small Bowel Adenocarcinoma), C50.A0-C50.A2 (related to Breast Cancer), D37.031, D37.032, D37.039 (related to Head and Neck Cancers), D37.3 (related to Appendiceal Neoplasms and Cancers)<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Phesgo | • Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include the number of days for approval and addition of Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist to the policy.<br>• To Breast Cancer, updating neoadjuvant/preoperative therapy and adjuvant therapy uses to be more inclusive of the pertuzumab/trastuzumab combination therapy settings within NCCN.<br>• Adding use as first-line maintenance therapy in combination with aromatase inhibitor with or without palbociclib in members with hormone receptor-positive disease following chemotherapy combo therapy to align with latest NCCN updates.<br>• To Dosage/Administration table, reformatting verbiage within the breast cancer maintenance dosing section for clarity.<br>• Adding the following ICD-10 codes per NCCN: C50.A0-C50.A2 (related to Breast Cancer).<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Ranibizumab | • Removing specific contraindications in criteria and replacing with general language indicating member does not have any FDA labeled contraindications. |

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| | • Updating the Length of Authorization section to include the number of days for approval.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Spevigo SC | • Updating Length of Authorization section to include number of days allowed for authorization durations.<br>• Adding weight required of greater than or equal to 40 kg for use in GPP.<br>• Updating criterion regarding providing support for concomitant therapy with immunomodulators.<br>• Removing quantity/dose requirements from initial/renewal criteria.<br>• Creating criteria blocks within the Initial criteria to separate Universal and Indication specific relevant criteria.<br>• Editing concomitant immunomodulatory therapy criteria for conciseness; intent remains the same.<br>• Consolidating renewal criteria to refer back to section III universal and indication specific criteria sections when repeated confirmation of criteria are required.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Spevigo IV | • Updating Length of Authorization section to include number of days allowed for authorization durations.<br>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.<br>• Adding weight required of greater than or equal to 40 kg for use in GPP.<br>• Updating criterion regarding providing support for concomitant therapy with immunomodulators<br>• Removing quantity/dose requirements from initial/renewal criteria as information is captured in the dosage/administration section.<br>• Creating criteria blocks within the Initial criteria to separate Universal and Indication specific relevant criteria and editing concomitant immunomodulatory therapy criteria for conciseness while maintaining the same intent.<br>• Revising the indication specific criteria for GPP flare to more closely align with the FDA labeling and latest NPF/AAD recommendations.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Trabectedin | • Updating policy title from “Yondelis” to “Trabectedin.”<br>• Updating Length of Authorization section to include the number of days for approval.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Trastuzumab IV | • To Breast Cancer, updating recurrent unresectable metastatic/inflammatory disease to separate out use in combination with pertuzumab, aromatase inhibition and with or without palbociclib as first line maintenance therapy and adding use for inflammatory disease for members with no response to preoperative systemic therapy. |

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| | • To CNS Cancers, adding note regarding interchangeability of products for intrathecal or intraventricular administration.<br>• To CRC, removing, combination use with lapatinib and removing requirement of "if intensive therapy is not recommended. Also allowing for use as subsequent therapy in any disease setting.<br>• To Billing Code section, adding NDC for Ontruzant.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Hercept Hylecta (trastuzumab SQ) | • 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.<br>• To the HER2-positive overexpression criteria table, updating language to align with NCCN updated verbiage by including ERBB2.<br>• Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.<br>• To ICD10 Table, adding C50.A0, A1, and A2 (related to Inflammatory Breast Cancer).<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Visudyne | • 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.<br>• Under universal criteria, removing any specific contraindications in criteria and replacing with general language indicating member does not have any FDA contraindications under the universal criteria.<br>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |
| Ziihera | • Updating Length of Authorization section to delineate between authorization durations for initial and renewal periods as well as include number of days allowed.<br>• To Universal Criteria, removing preclusion for use in members with untreated or symptomatic CNS metastases.<br>• To Billing Code/Availability, removing expired HCPCS code J9999 and C9302<br>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.<br>• To review the criteria in full, refer to the following link: https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates |