

# 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 05/01/2026

The following changes are being made to the listed medications and classes:

### PHARMACY BENEFIT

<p>Linzess Lubiprostone Prucalopride Trulance</p>	<ul style="list-style-type: none"> <li>• Updating initial criteria to indicate that only lubiprostone, Linzess and Trulance will be approved for the treatment of irritable bowel syndrome with constipation (IBS-C).</li> </ul>
<p>Anticonvulsants Step Therapy</p>	<ul style="list-style-type: none"> <li>• Updating policy to clarify that generic Qudexy XR is a second-line agent requiring trial and failure with at least two first-line agents or one second-line agent.</li> <li>• Adding prior authorization criteria for members who do not meet the automated step therapy requirements at the point-of-sale. The prior authorization criteria will mirror the step therapy requirements.</li> </ul>
<p>Fabhalta</p>	<ul style="list-style-type: none"> <li>• Updating initial criteria for primary immunoglobulin A nephropathy (IgAN) to include requirement that the requested medication is being used to reduce proteinuria.</li> <li>• Updating initial criteria for complement 3 glomerulopathy to include requirement that the member has been treated with a maximally tolerated</li> </ul>

	dose of an angiotensin-converting enzyme inhibitor (e.g., benazepril, lisinopril) or angiotensin receptor blocker (e.g., losartan, valsartan) prior to initiating treatment with Fabhalta.
Filspari	<ul style="list-style-type: none"> <li>Updating initial criteria to include requirements that member is at risk for disease progression and has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/minute/1.73 m<sup>2</sup>.</li> </ul>
Tarpeyo	<ul style="list-style-type: none"> <li>Updating initial criteria to include requirements that member is at risk for disease progression and has an estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/minute/1.73 m<sup>2</sup>.</li> </ul>
Nucala	<ul style="list-style-type: none"> <li>Updating minimum eosinophil count in initial COPD criteria to 300 cells per microliter.</li> </ul>
Sandostatin Sandostatin LAR Mycapssa Octreotide injection	<ul style="list-style-type: none"> <li>Updating initial and reauthorization criteria for diagnosis of acromegaly to require submission of chart notes or laboratory reports documenting laboratory and surgery/radiotherapy criteria are met.</li> </ul>
Somavert	<ul style="list-style-type: none"> <li>Updating initial and reauthorization criteria to require submission of chart notes or laboratory reports documenting laboratory and surgery/radiotherapy criteria are met.</li> </ul>
Vtama	<ul style="list-style-type: none"> <li>Updating initial criteria for plaque psoriasis to include minimum four-week trial of prerequisite topical therapy agent and removing allowance to bypass topical trial requirements if Vtama is being used on sensitive skin area.</li> </ul>
Zoryve	<ul style="list-style-type: none"> <li>Updating initial criteria for plaque psoriasis to include minimum four-week trial of prerequisite topical therapy agent and removing allowance to bypass topical trial requirements if Zoryve is being used on sensitive skin area.</li> </ul>

## MEDICAL BENEFIT

Ocular Disorders	<ul style="list-style-type: none"> <li>Criteria for Cimerli will be updated will be updated to align with that of Byooviz.</li> <li>Initial criteria for the following nonpreferred agents will be updated to require trial and failure with either Byooviz or Cimerli for shared indications: Lucentis, Vabysmo, Susvimo, Aflibercept (Eylea and biosimilars, Eylea HD) and Beovu. Trial and failure with bevacizumab will continue to be required for approval of nonpreferred agents.</li> <li>The following policies will be updated to reflect these changes: Ranibizumab, Vabysmo, Susvimo, Aflibercept, and Beovu.</li> <li>The impacted policies can be reviewed in full at the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Aranesp	<ul style="list-style-type: none"> <li>Updating “Non-Dialysis” to “non-ESRD” throughout policy to align with HCPCS code description.</li> </ul>



	<ul style="list-style-type: none"> <li>• Administrative changes to Length of Authorization section to delineate between authorization durations for initial and renewal period and to include number of days allowed for authorization durations.</li> <li>• To Universal Criteria, adding option for member to bypass adequate iron stores levels if on intravenous iron concurrently and removing footnote regarding this scenario.</li> <li>• To Anemia Due to Myeloproliferative Neoplasms - Myelofibrosis, updating wording to align with NCCN and updating criteria for patients with splenomegaly and constitutional symptoms currently controlled on a JAK inhibitor from use in combination with ruxolitinib to in combination with a JAK inhibitor per NCCN update.</li> <li>• To Renewal Criteria, updating list of unacceptable toxicities to better align with the package insert (PI) and other erythropoietin stimulating agents (ESA) policies.</li> <li>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Arcalyst	<ul style="list-style-type: none"> <li>• Administrative change to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Epoetin alfa	<ul style="list-style-type: none"> <li>• Updating “non-dialysis” to “non-ESRD” throughout policy to align with HCPCS code description.</li> <li>• Administrative changes to Length of Authorization section to delineate between authorization durations for initial and renewal period and to include number of days allowed for authorization durations.</li> <li>• To Universal Criteria, adding option for patient to bypass adequate iron stores levels if on intravenous iron concurrently and removing footnote regarding this scenario.</li> <li>• To Anemia Due to Myeloproliferative Neoplasms - Myelofibrosis, updating wording to align with NCCN and updating criteria for patients with splenomegaly and constitutional symptoms currently controlled on a JAK inhibitor from use in combination with ruxolitinib to in combination with a JAK inhibitor per NCCN update.</li> <li>• To Renewal Criteria, updating list of unacceptable toxicities to better align with the PI and other ESA policies.</li> <li>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Mircera	<ul style="list-style-type: none"> <li>• Updating “non-dialysis” to “non-ESRD” throughout policy to align with HCPCS code description.</li> </ul>



	<ul style="list-style-type: none"> <li>Administrative changes to Length of Authorization section to delineate between authorization durations for initial and renewal period and to include number of days allowed for authorization durations.</li> <li>To Universal Criteria, adding option for member to bypass adequate iron stores levels if on intravenous iron concurrently and removing footnote regarding this scenario.</li> <li>Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Rivfloza	<ul style="list-style-type: none"> <li>Administrative change to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>To max units (MU), updating “months” to “days.”</li> <li>Removing example of urinary oxalate reducing agents from Universal Criteria.</li> <li>To Appendix 1 - Covered Diagnosis Codes, adding codes E72.530, E72.538, and E72.539 to replace previous code of E72.53.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Adcetris	<ul style="list-style-type: none"> <li>Administrative changes to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>To universal criteria adding exception statement to CD30+ disease to allow for CD30 negative disease where specified.</li> <li>Removing ‘Primary’ from Cutaneous Lymphomas throughout policy based on NCCN.</li> <li>To Adult cHL, for use in combination with BrECADD, removing age range based on removal from NCCN recommendation.</li> <li>To T-cell Lymphomas, adding orphan drug designation symbol to Adult T-Cell Leukemia/Lymphomas and Extranodal NK/T-Cell Lymphomas.</li> <li>To Peripheral T-cell Lymphoma (PTCL), adding updated NCCN recommendations for use as single agent for relapsed or refractory disease as subsequent therapy OR as initial palliative intent therapy for Enteropathy-Associated T-cell Lymphoma, Monomorphic Epitheliotropic Intestinal T-cell Lymphoma, Nodal Peripheral T-cell Lymphoma with TFH phenotype, and Follicular T-cell Lymphoma.</li> <li>To PTCL, adding cyclophosphamide, doxorubicin, etoposide, prednisone regimen for use as initial therapy for previously untreated disease. Also adding this new combination regimen to dosing box and LoA section.</li> <li>To B-Cell lymphomas, updating to allow use for disease to be CD30 negative for DLBCL, HIV-related B-Cell Lymphomas and PTLID.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Anktiva	<ul style="list-style-type: none"> <li>Administrative changes to Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include</li> </ul>



	<p>number of days allowable, and to Initial and Renewal criteria to update 'coverage' to 'prior authorization validity'.</p> <ul style="list-style-type: none"> <li>• Adding Non-Quantitative Treatment Limitations (NQTL) Factor Checklist to appendix section.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Cerezyme	<ul style="list-style-type: none"> <li>• Adding FDA approved indication for the treatment of non-CNS manifestations of Type 1 or Type 3 Gaucher disease in adults and pediatric patients.</li> <li>• Removing the age requirement criteria.</li> <li>• Making editorial changes to the dosing table to align with the updated package labeling.</li> <li>• Updating the examples of unacceptable toxicity to align with the Warnings and Precautions section of the package insert.</li> <li>• Administrative changes to 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.</li> <li>• Administrative changes to Initial and Renewal criteria to update 'coverage' to 'prior authorization validity'.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Darzalex IV	<ul style="list-style-type: none"> <li>• Administrative change to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>• To multiple myeloma (MM), adding use in combination with teclistamab as an option for patients who have had prior therapy with lenalidomide and a proteasome inhibitor. A corresponding update was made to Dosage/Administration table.</li> <li>• Adding indication of HIV-Related B-Cell Lymphoma – plasmablastic lymphoma per NCCN 2A recommendation.</li> <li>• Corresponding updates were made to left-occiput anterior (LOA), Dosing Limits, Dosage/Administration, and ICD 10 code table (C83.30-C83.38, C83.398).</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Datroway	<ul style="list-style-type: none"> <li>• Administrative changes to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>• To Breast cancer, updating criteria for prior endocrine-based therapy to align more closely with package insert and NCCN.</li> <li>• To non-small cell lung cancer (NSCLC), removing exclusion for locoregional recurrence or symptomatic local disease without evidence of disseminated disease and adding EGFR mutations: S768I, L861Q, G719X, or exon 20 insertion.</li> <li>• Removing HCPCS Code C9174 and J9999 as these were discontinued 10/01/2025.</li> <li>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> </ul>



	<ul style="list-style-type: none"> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Enhertu	<ul style="list-style-type: none"> <li>Adding the FDA approved expanded indication for use in combination with pertuzumab for the first-line treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer as determined by an FDA-approved test.</li> <li>Administrative changes to 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.</li> <li>Administrative changes to Initial and Renewal criteria to update ‘coverage’ to ‘prior authorization validity’.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Erbix	<ul style="list-style-type: none"> <li>Administrative changes to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>Updating section heading to reflect new NCCN guideline for Appendiceal Neoplasms and Cancers. Additionally, to this section including recurrent, progressive metastatic peritoneal-only and extraperitoneal disease throughout, adding neoadjuvant therapy to BRAF V600 E disease, and adding additional treatment setting and regimens for KRAS/NRAS and BRAF V600E wild type disease.</li> <li>Removing footnote for MMR/MSI testing.</li> <li>To Head and Neck Cancers, adding Cancer of the Glottic Larynx, Supraglottic Larynx, and Occult primary cancers (non-HPV-positive) for use as sequential systemic therapy/radiation.</li> <li>Also to H&amp;N Cancer, removing performance status requirements from first line and subsequent therapy, and removing staging requirements to streamline criteria and align indication with guideline and other policies for H&amp;N Cancer.</li> <li>To non-small cell lung cancer (NSCLC), removing 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 no longer lists as 2B and to initial and subsequent therapy with lazertinib updated to allow with or without amivantamab.</li> <li>To ICD10 table, removing C44.0, C44.09, C77.0, C79.89, D37.01 and adding D37.3 (related to Appendiceal Neoplasms and Cancers), C05.2, D37.04, Z85.810, Z85.22, and Z85.818 (related to Head and Neck Cancer) per NCCN.</li> <li>Updating ICD-10 crosswalk (for PCM) list.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Ilaris	<ul style="list-style-type: none"> <li>Administrative changes to Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include number of days allowed for authorization durations.</li> <li>Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> </ul>



	<ul style="list-style-type: none"> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Inlexzo	<ul style="list-style-type: none"> <li>To Bladder Cancer, adding compendia symbol as Inlexzo is now noted in NCCN.</li> <li>To Billing Code section, adding for hospital use only to C9399 per IPD. To Appendix 1, removing Z85.51 as it is no longer listed in NCCN.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Jelmyto	<ul style="list-style-type: none"> <li>Administrative change to Length of Authorization section to delineate between authorization durations for initial and renewal periods and include number of days allowed, and to updating Prior Authorization validity verbiage.</li> <li>Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Keytruda IV	<ul style="list-style-type: none"> <li>Administrative change to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>To Urothelial Carcinoma (Bladder Cancer), adding the newly FDA approved neoadjuvant/adjuvant use in combination with enfortumab vedotin followed by single agent pembrolizumab in the adjuvant setting for the treatment of muscle invasive bladder cancer in cisplatin ineligible patients to all affected sections within the policy. Including a footnote to allow use in combination with enfortumab vedotin as second line therapy despite previous treatment with immunotherapy or chemotherapy (no prior enfortumab vedotin use) and to clarify use for primary carcinoma of the urethra as first-line metastatic or as second-line setting for recurrent or metastatic disease, all to align with national comprehensive cancer network (NCCN) recommendations.</li> <li>Adding a footnote to the Gastric, Esophageal, and Esophagogastric/ Gastroesophageal Junction Cancer sections as well as the MSI-H/dMMR and TMB-H sections to allow previous therapy with a programmed death (PD-1/PD-L1)-directed therapy if no disease progression in certain settings, per NCCN.</li> <li>To Head and Neck Cancers, updating criteria extensively for use per new NCCN guidelines.</li> <li>To chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), updating criteria to align with NCCN updates and adding a footnote indicating prior treatment could have included PD-1/PD-L1-directed therapy when used as additional therapy.</li> <li>To adult cHL, adding criteria for single agent use post-allogeneic cell transplant, adding to criteria regarding relapsed or refractory disease to allow use with or without prior checkpoint inhibitor exposure, and adding that use in primary therapy is allowable as single agent therapy with or without involved site radiation therapy (ISRT), all to align with NCCN.</li> <li>To NSCLC, removing 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 no longer lists as 2B.</li> <li>Making editorial change to bullet for neoadjuvant treatment to now clarify neoadjuvant treatment will be followed by adjuvant treatment.</li> </ul>



	<ul style="list-style-type: none"> <li>• Updating definition of stage IIIB disease and updating biomarker footnoted text and biomarker language within the criteria to align with latest NCCN recommendations/guidelines.</li> <li>• To Primary Cutaneous Lymphomas heading, removing “Primary” to align with NCCN guideline naming update.</li> <li>• To cutaneous squamous cell carcinoma (cSCC), adding use for satellitosis/in-transit metastatic disease that is unresectable or incompletely resected, per NCCN.</li> <li>• To Thymic Carcinoma, removing criteria for use in preoperative setting and updating criteria for second line setting to now be allowable for subsequent use instead, based on NCCN updates.</li> <li>• To Endometrial Carcinoma (Uterine Neoplasms), removing exclusion in the first line setting for presence of isolated metastasis as this is no longer 2B NCCN recommendation.</li> <li>• Adding new indication of Bone Cancer to align with NCCN new recommendations.</li> <li>• Updating use for Appendiceal Adenocarcinoma to now be named Appendiceal Neoplasms and Cancers to align with new NCCN nomenclature and updating clinical use settings within the criteria for POLE/POLD1 Mutation Cancers to align with NCCN updates.</li> <li>• To initial therapy for Thyroid Cancers under the TMB-H Cancer heading, updating the verbiage regarding radioactive iodine refractory disease to mirror NCCN recommendations.</li> <li>• Aligning the ICD-10 table with the latest NCCN recommended codes: Adding C05.2, D37.031, D37.032, D37.039, D37.04, Z85.12, Z85.22, Z85.810, Z85.818 (related to Head and Neck Cancers), D37.3, Z85.038 (related to Appendiceal Neoplasms and Cancers); Removed C00.0-C00.2, C44.00, C44.09, C77.0, C79.89, D37.01 (related to Head and Neck Cancers), C62 series of codes and Z85.47 (related to Testicular Cancer).</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Keytruda QLEX	<ul style="list-style-type: none"> <li>• Making changes throughout the policy to eliminate specific compendia-only supported criteria to instead align all indication-specific criteria with the FDA package insert supported information while also allowing any requests for Substitution/Switch-Therapy for Intravenous Pembrolizumab to be reviewed via criteria within the intravenous pembrolizumab policy.</li> <li>• Adding the Substitution/Switch-Therapy for Intravenous Pembrolizumab setting to the Length of Authorization and Dosage/Administration section which will route to the intravenous pembrolizumab policy for all applicable non-package insert supported criteria.</li> <li>• Administrative change to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>• To Urothelial Carcinoma, adding the newly FDA approved neoadjuvant/adjuvant use in combination with enfortumab vedotin followed by single agent pembrolizumab in the adjuvant setting for the treatment of muscle invasive bladder cancer in cisplatin ineligible patients to all affected sections within the policy.</li> </ul>



	<ul style="list-style-type: none"> <li>• Updating NDC descriptions for both vial formulations.</li> <li>• To Appendix 1, aligning ICD-10 codes with the intravenous pembrolizumab policy.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Lunsumio IV	<ul style="list-style-type: none"> <li>• Adding criteria stating that therapy will not be used concomitantly with subcutaneous mosunetuzumab to align with the newly created Lunsumio Velo (SQ) policy.</li> <li>• Clarifying that use for the treatment of Follicular Lymphoma is as a single agent to align with the package insert and NCCN.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
NPlate	<ul style="list-style-type: none"> <li>• Administrative changes to Length of Authorization section to delineate between authorization durations for initial and renewal periods, and to Initial and Renewal criteria to update 'coverage' to 'prior authorization validity'.</li> <li>• To universal criteria, updating statement regarding use of romiplostim not be used to normalize platelet count.</li> <li>• Adding new indication of Immune Checkpoint Inhibitor-Related Toxicities with pertinent criteria per 2A recommendation in national comprehensive cancer network (NCCN). Corresponding update was made to Length of Auth section, Dosing Limits section, and Dosage/Administration table.</li> <li>• Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>• Removing CMS reference A57160 (Jurisdiction 15) as it is not applicable to Nplate.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Onivyde	<ul style="list-style-type: none"> <li>• Administrative changes to Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include number of days allowed for authorization durations.</li> <li>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Opdivo IV	<ul style="list-style-type: none"> <li>• Administrative change to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>• To Bone Cancers, updating options for use based on cell histology and adding option for use as a single agent or in combination with sunitinib for dedifferentiated chondrosarcoma. Updating the length of authorization section accordingly.</li> <li>• To Cervical cancer, adding option for use in combination with ipilimumab for recurrent or metastatic adenocarcinoma, adenosquamous carcinoma, or squamous cell carcinoma.</li> <li>• Adding new setting for use in persistent, recurrent/metastatic small cell neuroendocrine carcinoma (NECC) per national comprehensive cancer network (NCCN) recs.</li> </ul>



- Updating Indication heading of Appendiceal Adenocarcinoma to Appendiceal Neoplasms and Cancers per changes in NCCN.
- Updating criteria to allow treatment as a single agent or in combination with ipilimumab for recurrent, progressive, peritoneal-only or extraperitoneal disease.
- To Esophageal, Esophagogastric & Gastric cancers, adding allowance for use in patients with either no prior checkpoint inhibitor or no tumor progression while on checkpoint inhibitor therapy when used in the first- or subsequent-line settings.
- To squamous cell carcinoma of the head and neck (SCCHN), adding new option for use in combination with cetuximab for unresectable, recurrent, persistent, or metastatic disease.
- To Adult CHL, making multiple changes to incorporate recommendations from the latest NCCN guideline updates for all regimens.
- To RCC, making editorial change to move renal cell carcinoma (RCC) note from triangle footnote box up to the criteria.
- To non-small cell lung cancer (NSCLC), removing 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 no longer lists as 2B.
- To neoadjuvant treatment, adding option for use in combination with platinum and docetaxel per changes in NCCN.
- Updating biomarker footnoted text to align with latest NCCN recommendations/guidelines.
- Updating heading of Endometrial Carcinomas to Uterine Neoplasms as NCCN now allows use for treatment of uterine sarcomas as well as endometrial carcinomas. Updating criteria to align with latest version of NCCN guidelines.
- To Vulvar and Vaginal cancers, adding option for use in combination with ipilimumab as subsequent treatment of recurrent or metastatic disease.
- To chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), updating criteria to align with NCCN updates and adding a footnote indicating prior treatment could have included PD-1/PD-L1-directed therapy when used as additional therapy.
- To the dosing table, adding dosing for treatment of Bone Cancer in combination with sunitinib.
- Adding option for use in combination with ipilimumab for treatment of vaginal, vulvar or cervical cancers.
- Streamlining dosing options for treatment of appendiceal neoplasms & cancers.
- To Appendix 1, removing ICD-10 codes C00.0-C00.2, C44.00, C44.09, C77.0 , C79.89, D37.01. Added ICD-10 codes C05.2, D37.04, Z85.810, Z85.818 & Z85.22 (related to H&N Cancers), D37.3 & Z85.038 (related to Appendiceal Neoplasms). 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>



Opdivo Qvantig	<ul style="list-style-type: none"> <li>• Making changes throughout the policy to eliminate specific compendia-only supported criteria to instead align all indication-specific criteria with the FDA package insert.</li> <li>• Adding the Substitution/Switch-Therapy for Intravenous Nivolumab setting to the Length of Authorization and Dosage/Administration section which will route to the intravenous nivolumab policy for all applicable non-package insert supported criteria.</li> <li>• Administrative change to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>• To Substitution/Switch therapy, removing list of indications supported by NCCN as these were not all inclusive anyway.</li> <li>• Adding FDA expanded indication for use in pediatric patients at least 12 years of age for treatment of melanoma or MSI-H/dMMR colorectal cancer.</li> <li>• To Renewal criteria, updating list of unacceptable toxicities to better align with the package insert (PI).</li> <li>• To Appendix 1, aligned ICD-10 codes with the Opdivo IV policy.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Oxlumo	<ul style="list-style-type: none"> <li>• Administrative changes to Length of Authorization section to include the number of days allowed and delineate between authorization durations for initial and renewal periods.</li> <li>• To max units (MU), updating months to days to streamline billing.</li> <li>• Adding Appendix A - Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>• To Appendix 1 - Covered Diagnosis Codes, updating to add codes E72.530, E72.538, and E72.539 to replace previous code of E72.53.</li> <li>• Adding disclaimer note to Max Units section denoting that max units do not reflect the max dosing limits in the package insert.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Padcev	<ul style="list-style-type: none"> <li>• Administrative change to Length of Authorization section to delineate between authorization durations for initial and renewal periods as well as to include number of days allowed.</li> <li>• To Bladder Cancer, removing line of therapy for use in combination with pembrolizumab to better streamline criteria as NCCN now allows in both first and second line. Adding new FDA indication for use in combination with pembrolizumab as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment for the treatment of MIBC in cisplatin ineligible patients. Adding dosing for the new indication to the dosing table and including in Length of Authorization section.</li> <li>• To bladder cancer for use as a single agent, adding option to use in second-line therapy as NCCN now allows, and adding footnote per NCCN regarding use in second line therapy which applies to both single agent and combination use.</li> <li>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>



Perjeta	<ul style="list-style-type: none"> <li>• Adding the expanded indication for use in combination with fam-trastuzumab deruxtecan for the first-line treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer as determined by an FDA-approved test. Updating the dosing table to reflect the addition of this new indication for use.</li> <li>• Administrative changes to 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 as a part of the global changes being made across all policies.</li> <li>• Administrative changes to Initial and Renewal criteria to update ‘coverage’ to ‘prior authorization validity’.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Rybrevant IV	<ul style="list-style-type: none"> <li>• Adding criteria stating that therapy will not be used concomitantly with subcutaneous amivantamab to align with the newly created Rybrevant Faspro (SQ) policy.</li> <li>• Administrative changes to Length of Authorization section to include the number of days for approval and addition of Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist to the policy as a part of the global changes being made across all policies.</li> <li>• Administrative changes to Initial and Renewal criteria to update ‘coverage’ to ‘prior authorization validity’.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Trodelvy	<ul style="list-style-type: none"> <li>• Administrative changes to Length of Authorization section to delineate between authorization durations for initial and renewal periods and to include number of days allowed for authorization durations.</li> <li>• To Initial Approval Criteria adding primary prophylaxis with a G-CSF starting in first cycle of treatment in all patients at increased risk of febrile neutropenia to align with PI update.</li> <li>• To Urothelial Cancer per NCCN, updating to allow use for subsequent therapy in patients previously treated with platinum chemotherapy and PD-1/PD-L1 therapy.</li> <li>• Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>• To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Uplizna	<ul style="list-style-type: none"> <li>• Adding the expanded indication for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive.</li> <li>• Updating the Length of Authorization section to reflect the addition of this new indication.</li> <li>• Adding ICD-10 codes G70.00 and G70.01 for gMG.</li> <li>• Administrative change to the Length of Authorization section to include the number of days for approval as part of the global change being made across all policies.</li> </ul>



	<ul style="list-style-type: none"> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Yervoy	<ul style="list-style-type: none"> <li>Administrative change to Length of Authorization section to include number of days allowed for authorization durations.</li> <li>To Bone Cancers, updating options for use to be sorted by cell histology.</li> <li>Updating Indication heading of Appendiceal Adenocarcinoma to Appendiceal Neoplasms and Cancers per changes in national comprehensive cancer network (NCCN). Updating criteria to allow use in combination with nivolumab for recurrent, progressive, peritoneal-only or extraperitoneal disease and to define use based on history with or without checkpoint inhibitors.</li> <li>To Esophageal, Esophagogastric &amp; Gastric cancers, adding allowance for use in patients with either no prior checkpoint inhibitor or no tumor progression while on checkpoint inhibitor therapy when used in the first- or second-line settings.</li> <li>To renal cell carcinoma (RCC), making editorial change to move RCC note from triangle footnote box up to the criteria.</li> <li>To non-small cell lung cancer (NSCLC), removing 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 no longer lists as 2B.</li> <li>Updating biomarker footnoted text to align with latest NCCN recommendations/guidelines.</li> <li>Adding new indications of vulvar cancer, vaginal cancer, cervical cancer and uterine neoplasms with corresponding criteria, dosing and ICD-10 codes per NCCN.</li> <li>Updating Length of authorization and max units sections to accommodate new indications.</li> <li>To Appendix 1, added ICD-10 codes C51.0-C51.2, C51.8, C51.9 (related to vulvar cancer), C52 (related to vaginal cancer), C53.0, C53.1, C53.8, C53.9 (related to cervical cancer), C54.0-C54.3, C54.8, C54.9, C55, Z85.42 (related to endometrial cancer), and D37.3, Z85.038 (related to Appendiceal Neoplasms). Updated ICD-10 crosswalk (for PCM) list.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>
Zusduri	<ul style="list-style-type: none"> <li>To Initial Criteria, removing criteria on concurrent use with Jelmyto since criteria already notes use as a single agent.</li> <li>Editorial changes throughout policy including to Renewal Criteria on duration of authorization.</li> <li>From Billing Code Section, removing discontinued unclassified code J9999.</li> <li>Adding Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist.</li> <li>To review the criteria in full, refer to the following link: <a href="https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates">https://gatewaypa.com/policydisplay/57/mgb-upcoming-policy-updates</a></li> </ul>

