### Medication

<table>
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<tr>
<th>Medication</th>
<th>FDA Indications</th>
<th>MFC Specifications</th>
</tr>
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<tbody>
<tr>
<td><strong>Aimovig</strong>&lt;br&gt;(erenumab-aooe)</td>
<td>Indicated for the preventive treatment of migraine in adults.</td>
<td>1. Rx by Neurologist 2. Member must have tried and failed at least 2 previous migraine prophylaxis medications. Examples of migraine prophylaxis medications include, but are not limited to, divalproex, metoprolol, propranolol, timolol, topiramate, amitriptyline, venlafaxine, atenolol.</td>
</tr>
<tr>
<td><strong>Alecensa</strong>&lt;br&gt;(alectinib)</td>
<td>Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.</td>
<td>Rx by Oncologist</td>
</tr>
<tr>
<td><strong>Alunbrig</strong>&lt;br&gt;(brigatinib)</td>
<td>Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.</td>
<td>Rx by Oncologist</td>
</tr>
<tr>
<td><strong>Amitiza</strong>&lt;br&gt;(lubiprostone)</td>
<td>Indicated for: 1. chronic idiopathic constipation (CIC) in adults. 2. opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Limitations of Use: Effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established. 3. irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old.</td>
<td>Failure of at least 2 of the following: docusate, sennosides, polyethylene glycol 3350, lactulose, methylcellulose</td>
</tr>
<tr>
<td><strong>Ampyra</strong>&lt;br&gt;(dalfampridine)</td>
<td>Indicated to help improve walking in adults with MS.</td>
<td>1. Rx by Neurologist. 2. Documentation of MS with ambulatory dysfunction, but must be able to walk 25 feet within 8-45 seconds at baseline.</td>
</tr>
</tbody>
</table>

*Note: Although every effort is made to keep this FDA indication list up to date, please consult the web link in the far right column for the most accurate information.*
| **3.** | Members must have a baseline gait assessment by PT within 90 days of beginning Ampyra. |
| **4.** | Members must have a repeat evaluation after 3 months on Ampyra. Improvement in walking speed must be documented in order to obtain further refills. |
| **5.** | Members must not have a history of seizure disorder or renal impairment. |

### Balversa
*eriadafitinib)*

- Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.
- Rx by Oncologist

### Bethkis
*tobramycin inh sol)*

- Indicated for management of cystic fibrosis patients with *Pseudomonas aeruginosa*. ***Safety and efficacy have not been demonstrated in patients under the age of six years, patients with a forced expiratory volume in one second (FEV1) less than 40% or greater than 80% predicted, or patients colonized with Burkholderia cepacia.***
- Rx by Pulmonologist

### Bosulif
*bosutinib)*

- Indicated for the treatment of adult patients with:
  1. Newly-diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML). This indication is approved under accelerated approval based on molecular and cytogenetic response rates. Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial.
  2. Chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.
- Rx by Oncologist

### Botox
*onabotulinumtoxin A)*

- Indicated for:
  1. treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
  2. treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- Rx by Neurologist, Urologist, Ophthalmologist

- Botox will **NOT** be approved for cosmetic purposes.
<p>| | | |</p>
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<tbody>
<tr>
<td>3.</td>
<td>prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).</td>
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<tr>
<td>4.</td>
<td>treatment of spasticity in adult patients.</td>
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<tr>
<td>5.</td>
<td>treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain.</td>
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<tr>
<td>6.</td>
<td>treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients.</td>
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<tr>
<td>7.</td>
<td>treatment of blepharospasm associated with dystonia in patients ≥12 years of age.</td>
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<tr>
<td>8.</td>
<td>treatment of strabismus in patients ≥12 years of age.</td>
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</table>

**Braftovi** *(encorafenib)*  
Indicated, in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

**Cabometyx** *(cabozantinib)*  
Indicated for the treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy.

**Cometriq** *(cabozantinib)*  
Indicated for treatment of progressive, metastatic medullary thyroid cancer.

**Cotellic** *(cobimetinib)*  
Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

**Cutaquig** *(immune globulin subcutaneous (human) - hipp)*  
Indicated for primary humoral immunodeficiency in adults.

**DDAVP** *(desmopressin)*  
See Desmopressin Nasal Spray Products

**DESMOPRESSIN NASAL SPRAY PRODUCTS:**

**DDAVP** is indicated for:
1. treatment of central Diabetes Insipidus.
2. treatment of transient polyuria and polydipsia post head trauma or neurosurgery.

**Stimate** is indicated for:
1. hemophilia A with Factor VIII coagulant activity levels greater than 5% - will stop bleeding in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding.

**STIMATE:** Hemophilia A with factor VIII coagulant activity greater than 5%:
- peri-operatively to prevent bleeding
- to treat spontaneous or trauma induced bleeding

***Note- Patients with factor VIII levels equal to or less than 5% or patients who have factor VIII antibodies are not candidates for the drug. It is

**Rx by Oncologist**  
BRAFTOVI PI

**Rx by Oncologist**  
CABOMETYX PI

**Rx by Oncologist**  
COMETRIQ PI

**Rx by Oncologist**  
COTELLCI PI

**Rx by Immunologist**  
CUTAQUIG PI

**Rx by Oncologist**  
DDAVP FDA PI

**STIMATE PI**
<table>
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<tr>
<th>Drug</th>
<th>Indication</th>
<th>Additional Information</th>
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</thead>
<tbody>
<tr>
<td><strong>Dificid</strong>&lt;br&gt;(fidaxomicin)</td>
<td>Indicated for the treatment of <em>Clostridium difficile</em>-associated diarrhea in adults ($\geq$18 years of age).</td>
<td>Pt must have documented failures with both metronidazole and vancomycin, or contraindication(s) to the use of these agents.</td>
</tr>
</tbody>
</table>
| **Doptelet**<br>(avatrombopag) | Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. | 1. Rx by Hematologist  
2. A recent (less than 1 month old) platelet count must be supplied with the clinical request, as well as information regarding the planned procedure. | **DOPTELET PI**                                                                                     |
| **Dupixent**<br>(dupilumab) | **Indicated for:**  
1. treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.  
2. add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. | Rx by Allergist or Dermatologist                                                                                                                              | **DUPIXENT PI**                                                                                     |
<p>| <strong>Elgard</strong>&lt;br&gt;(leuprolide SQ) | see <strong>Leuprolide</strong>                                                                 |                                                                                                                                                                                                                     |                                                                                                      |
| <strong>Elzonris</strong>&lt;br&gt;(tagraxofusp-erzs) | Indicated for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older. | Rx by Oncologist                                                                                                                                             | <strong>ELZONRIS PI</strong>                                                                                     |</p>
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<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Prescriber</th>
<th>Notes</th>
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<tbody>
<tr>
<td><strong>Endari</strong> (L-glutamine)</td>
<td>Indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.</td>
<td>Rx by Hematologist</td>
<td>ENDARI PI</td>
</tr>
<tr>
<td><strong>Erwinaze</strong> (asparaginase <em>Erwinia chrysanthemi</em>)</td>
<td>Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with ALL who have developed hypersensitivity to <em>E. coli-</em> derived asparaginase.</td>
<td>Rx by Oncologist</td>
<td>ERWINAZE PI</td>
</tr>
<tr>
<td><strong>Esbriet</strong> (pirfenidone)</td>
<td>Indicated for the treatment of idiopathic pulmonary fibrosis.</td>
<td>Rx by Pulmonologist or Cardiologist</td>
<td>ESBRIET PI</td>
</tr>
<tr>
<td><strong>Fasenra</strong> (benralizumab)</td>
<td>Indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.</td>
<td>Rx by Pulmonologist or Allergist</td>
<td>FASENRA PI</td>
</tr>
<tr>
<td><strong>fentanyl</strong></td>
<td>Indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Patients considered opioid-tolerant are those taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid. <strong>Limitations of use:</strong> Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve DURAGESIC [fentanyl] for use in patients for whom alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. DURAGESIC [fentanyl] is not indicated as an as-needed (prn) analgesic.</td>
<td>The Department of Health and Mental Hygiene has mandated that all long-acting opioids require Prior Authorization (PA) as of July 1, 2017. The PA form can be accessed using the following link: OPIOID PRIOR AUTHORIZATION FORM</td>
<td>fentanyl PI</td>
</tr>
<tr>
<td><strong>Firazyr</strong> (icatibant)</td>
<td>Indicated for the treatment of acute attacks of hereditary angioedema in adults ≥18 years of age (self-administered by the patient).</td>
<td>Rx by Allergist or ENT</td>
<td>FIRAZYR PI</td>
</tr>
<tr>
<td><strong>Gralise</strong> (gabapentin)</td>
<td>Indicated for the management of Postherpetic Neuralgia (PHN).</td>
<td></td>
<td>GRALISE PI</td>
</tr>
<tr>
<td><strong>Growth Hormone</strong></td>
<td>See Norditropin; See Serostim</td>
<td></td>
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</tr>
<tr>
<td><strong>Haegarda</strong> (C1 Esterase Inhibitor SubQ (Human))</td>
<td>Indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients.</td>
<td>Rx by Allergist/Immunologist</td>
<td>HAEGARDA PI</td>
</tr>
<tr>
<td><strong>Hycamtin caps</strong> (topotecan)</td>
<td>Indicated for treatment of patients with relapsed small cell lung cancer.</td>
<td>Rx by Oncologist</td>
<td>HYCAMTIN PI</td>
</tr>
</tbody>
</table>

July 17, 2019
| **Ibrance**  
( palbociclib) | Indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:  
1. an aromatase inhibitor as initial endocrine based therapy in postmenopausal women; or  
2. fulvestrant in women with disease progression following endocrine therapy. | Rx by Oncologist | **IBRANCE PI** |
| --- | --- | --- | --- |
| **Iclusig**  
( ponatinib) | Indicated for:  
1. treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated.  
2. treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). | Rx by Oncologist | **ICLUSIG PI** |
| **Imbruvica**  
( ibrutinib) | Indicated for:  
1. Mantle cell lymphoma (MCL) who have received at least one prior therapy. Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.  
2. Chronic lymphocytic leukemia/small lymphocytic lymphoma.  
4. Waldenström’s macroglobulinemia (WM).  
5. Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.  
6. Chronic graft versus host disease after failure of one or more lines of systemic therapy. | Rx by Oncologist | **IMBRUVICA PI** |
| **Insulin Pens** | Age 0-18: Insulin pens will be provided for members ages 0-18 years of age.  
Age 19 and older: **Basaglar** and **Tresiba** pens do NOT require prior authorization and are available to all members. **All other insulin pens require prior authorization.** | --- | --- |
The MFC Insulin Pen Policy (Policy 211) states that insulin pens will be approved for members who cannot properly use and draw up insulin from vials into syringes or whose caregiver(s) cannot properly use and draw up insulin from vials into syringes including members with:

1) Poor visual acuity,
2) Poor manual dexterity, or
3) Limited ability to learn proper technique due to educational challenges

Medical records may be required to support the PA request.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indicated for:</th>
<th>Rx by Healthcare Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jakafi (ruxolitinib)</td>
<td>1. treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis. 2. treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.</td>
<td>Hematologist/Oncologist</td>
</tr>
<tr>
<td>Jardiance (empagliflozin)</td>
<td>1. as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. 2. to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.</td>
<td>Patients must have known cardiovascular disease to qualify for Jardiance.</td>
</tr>
<tr>
<td>Jivi (empagliflozin)</td>
<td>Recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: 1. On-demand treatment and control of bleeding episodes. 2. Perioperative management of bleeding. 3. Routine prophylaxis to reduce the frequency of bleeding episodes.</td>
<td>Hematologist</td>
</tr>
<tr>
<td>Juxtapid (lomitapide)</td>
<td>Indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-highdensity lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).</td>
<td>Cardiology or Endocrinologist</td>
</tr>
<tr>
<td>Jynarque (tolvaptan)</td>
<td>Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).</td>
<td>Nephrologist</td>
</tr>
<tr>
<td>Kalydeco (ivacaftor)</td>
<td>Indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. If the patient’s genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR.</td>
<td>Pulmonologist</td>
</tr>
</tbody>
</table>
Kisqali (ribociclib)

Indicated in combination with:
1. an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy; or
2. fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.

Kymria (tisagenlecleucel)

Indicated for:
1. Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
2. Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Limitation of Use: Kymria is not indicated for treatment of patients with primary central nervous system lymphoma (1.2)

In accordance with criteria developed by the Maryland Medicaid Program, MedStar Family Choice considers Kymria medically necessary when all of the following conditions are met:
1. Recipient has relapsed or refractory B-cell ALL, defined as
   a. Second or greater bone marrow relapse; OR
   b. Any bone marrow relapse after allogeneic stem cell transplantation; OR
   c. Primary refractory as defined by not achieving a complete remission after 2 cycles of a standard chemotherapy regimen or chemorefractory as defined by not achieving a complete remission after 1 cycle of standard chemotherapy for relapsed leukemia; OR
   d. Patients with Philadelphia chromosome positive (Ph+) ALL are eligible if they are intolerant to or have failed 2 lines of tyrosine kinase inhibitor therapy (TKI), or if TKI therapy is contraindicated; AND
2. Recipient is 25 years of age or younger; AND
3. Documentation of CD19 tumor expression; AND
4. Performance score on Karnofsky or Lansky Scale is greater than or equal to 50%; AND
5. Life expectancy > 12 weeks; AND
6. Adequate cardiac, pulmonary, and other organ function (as determined by protocol from treatment facility); AND
7. The treatment facility that dispenses and administers Kymria is enrolled and complies with the Risk Evaluation and Mitigation Strategy; AND
8. One-time, single administration with dosing in accordance with the FDA label.
Kymriah is considered investigational and not medically necessary when the above medically necessary criteria are not met, and for all other indications, including but not limited to:

1. Isolated extra-medullary disease relapse; or
2. Patients with Burkitt’s lymphoma/leukemia (i.e. patients with mature B-cell ALL, leukemia with B-cell [sig positive and kappa or lambda restricted positivity] ALL, with FAB L3 morphology and /or a MYC translocation); or
3. Prior malignancy, except carcinoma in situ of the skin or cervix treated with curative intent and with no evidence of active disease; or
4. Treatment with any other chimeric antigen receptor therapy or genetically modified T cell therapy; or
5. Any active uncontrolled infection; or
6. Hepatitis B or C (if viral load is detectable); or
7. Human Immunodeficiency Virus (HIV); or
8. Presence of grade 2 to 4 acute or extensive chronic graft-versus-host disease (GVHD); or
9. Active CNS involvement by malignancy, defined by CNS-3 per NCCN guidelines.

<table>
<thead>
<tr>
<th>LEUPROLIDE PRODUCTS:</th>
<th>Indicated for:</th>
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<th>LEUPROLIDE PRODUCTS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligard (leuprolide SQ)</td>
<td>1. palliative treatment for advanced prostate cancer (Eligard).</td>
<td>ELIGARD PI</td>
<td>LUPRON 3.75 mg PI</td>
</tr>
<tr>
<td>Lupron (leuprolide acetate)</td>
<td>2. treatment of pediatric patients with central precocious puberty (Lupron Depot-PED).</td>
<td>LUPRON DEPOT 11.25 MG PI</td>
<td>LUPRON DEPOT-PED PI</td>
</tr>
<tr>
<td>Lupron Depot (leuprolide acetate for depot suspension)</td>
<td>3. treatment of endometriosis (Lupron and Lupron Depot).</td>
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</tr>
<tr>
<td>Lupron Depot-PED (leuprolide acetate for depot suspension)</td>
<td>4. uterine leiomyomata (fibroids) along with concurrent iron therapy in preparation for surgery [duration of treatment should be for 6 months or less (Lupron and Lupron Depot)].</td>
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</table>

Libtayo (cemiplimab-rwlc) | Indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. | LIBTAYO PI |

Linzess (linaclotide) | Indicated for: | LINZESS PI |
<table>
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<tbody>
<tr>
<td>1. irritable bowel syndrome with constipation.</td>
<td>Failure of at least 2 of the following: docusate, sennosides, polyethylene glycol 3350, lactulose, methylcellulose</td>
<td></td>
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<tr>
<td>2. chronic idiopathic constipation.</td>
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LO Loestrin Fe | See Oral Contraceptive | LO LOESTRIN PI |
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lovaza (omega-3-acid ethyl esters)</td>
<td>Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.</td>
</tr>
<tr>
<td>Lumoxiti (moxetumomab pasudotox-tdfk)</td>
<td>Indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least 2 prior systemic therapies, including treatment with a purine nucleoside analog.</td>
</tr>
<tr>
<td>Lorbrena (lorlatinib)</td>
<td>Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on: • crizotinib and at least one other ALK inhibitor for metastatic disease; or • alectinib as the first ALK inhibitor therapy for metastatic disease; or • ceritinib as the first ALK inhibitor therapy for metastatic disease</td>
</tr>
<tr>
<td>Lupron and Lupron Depot</td>
<td>See Leuprolide</td>
</tr>
<tr>
<td>Lynparza (olaparib)</td>
<td>Indicated for: 1. First-Line Maintenance BRCAm Advanced Ovarian Cancer- For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients with gBRCAm advanced epithelial ovarian, fallopian tube or primary peritoneal cancer for therapy based on an FDA-approved companion diagnostic for LYNPARZA. 2. Maintenance Recurrent Ovarian Cancer- For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. 3. Advanced gBRCAm Ovarian Cancer- For the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm)</td>
</tr>
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</table>
advanced ovarian cancer who have been treated with 3 or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

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<tr>
<th><strong>Macrilen</strong> (macimorelin)</th>
<th>Indicated for the diagnosis of adult growth hormone deficiency.</th>
<th>Rx by Endocrinologist</th>
</tr>
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</table>

**Mavyret** (glecaprevir and pibrentasvir)

MAVYRET is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). MAVYRET is also indicated for the treatment of adult patients with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

**Please note:**
The Maryland Department of Health (MDH) has **MANDATED** a test of viral load after 2-4 weeks on treatment. If this check is not completed, medication refills will NOT be authorized after week 8 of treatment. This is a MDH requirement and as such, MFC does not have the ability to waive this testing under any circumstances. Viral load testing is also mandatory at 12 weeks and 24 weeks (for extended regimens). Lastly, viral load testing MUST be completed 12 weeks after therapy has ended (to assess SVR).

**Please submit:**
A COMPLETED PRIOR AUTHORIZATION FORM (see link below) via FAX to 410-933-2205

| **Mekinist** (trametinib) | Indicated:
1. as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
2. in combination with dabrafenib, for the treatment of patients with:
   - unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
   - patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection.
   - patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. | Rx by Oncologist |
|----------------------------|-----------------------------------------------------------------------------------------------------------------|-------------------|

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<tr>
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<th><strong>SEE SPECIAL NOTE REGARDING WEEK 4 VIRAL LOAD TESTING</strong></th>
<th><strong>MEKINST PI</strong></th>
</tr>
</thead>
</table>

To view the most up to date DHMH treatment criteria, follow the link below:

**MDH TREATMENT CRITERIA**
### Mektovi
**binimetinib**
Indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.
Rx by Oncologist

### methadone (for pain)
Indicated for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

#### Limitations of Use
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioids, reserve methadone hydrochloride tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Methadone hydrochloride tablets are not indicated as an as needed (prn) analgesic.

The Department of Health and Mental Hygiene has mandated that all long-acting opioids require Prior Authorization (PA) as of July 1, 2017. The PA form can be accessed using the following link:
[OPIOID PRIOR AUTHORIZATION FORM](#)

### Minastrin 24 Fe
**norethindrone, ethinyl estradiol and ferrous fumarate**
See Oral Contraceptive

***CHEWABLE***

### Movantik
**naloxegol**
Indicated for the treatment of opioid-induced constipation in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
Failure of at least 2 of the following: docusate, sennosides, polyethylene glycol 3350, lactulose, methylcellulose

### MS Contin
**morphine sulfate controlled release**
Indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

#### Limitations of Use
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve MS CONTIN for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. MS CONTIN for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

The Department of Health and Mental Hygiene has mandated that all long-acting opioids require Prior Authorization (PA) as of July 1, 2017. The PA form can be accessed using the following link:
[OPIOID PRIOR AUTHORIZATION FORM](#)

### July 17, 2019
<table>
<thead>
<tr>
<th>Drug</th>
<th>Indicated for:</th>
<th>Rx by:</th>
</tr>
</thead>
</table>
| Natazia (estradiol valerate  | 1.  use by women to prevent pregnancy.  
| and estradiol valerate/dienogest)  | 2.  treatment of heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception. | Endocrinologist         |
| Norditropin (somatropin (fDNA | 1.  treatment of children with growth failure due to growth hormone deficiency (GHD), short stature associated with Noonan syndrome, short stature | Endocrinologist         |
| origin) injection           | associated with Turner syndrome and short stature born SGA with no catch-up growth by age 2 to 4 years.  
|                             | 2.  treatment of adults with either adult onset or childhood onset GHD.                                                                           |                         |
| Noxfil (posaconazole)       | 1.  prophylaxis of invasive *Aspergillus* and *Candida*, ≥13 years of age, who are at high risk of developing these infections due to being severely immunocompromised (such as from: stem cell transplant with GVHD or prolonged neutropenia from chemotherapy).  
|                             | 2.  oropharyngeal candidiasis (OPC), including infections refractory to itraconazole and/or fluconazole.                                           | ID                      |
| Nucala (mepolizumab)        | 1.  add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.  
|                             | 2.  treatment of adult patients with eosinophilic granulomatosis with polyangiitis.                                                              | Allergist or Pulmonologist |
| Ofev (nintedanib)           | Indicated for the treatment of idiopathic pulmonary fibrosis.                                                                                    | Pulmonologist           |
| Onpattro (patisiran)        | Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.                                    | Rheumatology or Neurology |
**OPIOIDS**

**PRIOR AUTHORIZATION TERMS**

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**IMPORTANT INFORMATION ABOUT PRESCRIBING OPIOIDS FOR MEDSTAR FAMILY CHOICE MEMBERS**

**EARLY REFILL REQUESTS**

“Early” Opioid Refills Will No Longer be Covered by MedStar Family Choice - Effective 1/1/2019

Beginning 1/1/2019, MedStar Family Choice will not authorize early refills of controlled medications. Specifically, MedStar Family Choice will not approve early refills, override Managed Drug Limitations (MDL), replace lost/stolen medications, or provide early refills for travel for controlled medications. Exceptions may be granted if a member is receiving controlled medication(s) for cancer treatment, sickle cell disease, or is in hospice/receiving palliative care.

**PRIOR AUTHORIZATION**

Prior Authorization will be required for:

- Prescriptions > 50 MME/day or more than 7 day for an opioid naïve patient (no opioids taken in the previous 90 days or one ≤ 50 MME per day, ≤ 7 day prescription taken in the previous 90 days) as described in **Section I** below.
- opioid experienced patients as described in **Section II** below.

**SECTION I. OPIOID NAÏVE PATIENTS (defined as: no opioids in the previous 90 days or one fill of ≤ 50 MME per day for ≤ 7 days prescription taken in the previous 90 days)**

A “new” prescription means that a patient has not had an opioid medication filled under MedStar Family Choice in the preceding 90 days or had one short-acting opioid at ≤ 50 morphine equivalents per day for 7 or fewer days in previous 90 days. New prescriptions for more than 7-days’ supply or greater than 50 MME per day will require Prior Authorization. It is our hope that limiting opioid quantities to a 7-day supply will discourage abuse, both by our patients and by the community at large. This change is also consistent with Medicare policy (effective 2019) which limits opioid naïve patients to a 7-day supply.

**According to the CDC 2016 Guidelines for Prescribing Opioids, “When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.”**
Three days or less will often be sufficient; more than seven days will rarely be needed.”
Examples of a typical 3-day supply and a 7-day supply of frequently prescribed opioids are below:

<table>
<thead>
<tr>
<th>Medication</th>
<th>3-day supply quantity*</th>
<th>7-day supply quantity* (maximum allowable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROMORPHONE TAB 2MG</td>
<td>18 tablets</td>
<td>42 tablets</td>
</tr>
<tr>
<td>MORPHINE SULFATE TAB 15MG</td>
<td>18 tablets</td>
<td>42 tablets</td>
</tr>
<tr>
<td>OXYCODONE SOLUTION 5MG/5ML</td>
<td>180 mL</td>
<td>420 mL</td>
</tr>
<tr>
<td>OXYCODONE TAB 5MG</td>
<td>18 tablets</td>
<td>42 tablets</td>
</tr>
<tr>
<td>TRAMADOL HCL TAB 50MG</td>
<td>18 tablets</td>
<td>42 tablets</td>
</tr>
</tbody>
</table>

*Quantities are based on starting dose recommendations in the respective FDA Package Inserts for each medication.

Please contact MedStar Family Choice at 800-905-1722, option 2, for Prior Authorization of new opioid prescriptions that exceed the limits. Should you have any questions or concerns about this new policy, please call Dr. Danielle Gerry at 410-933-2295.

MedStar Family Choice strongly encourages you to prescribe the least amount of opioid at the lowest dose possible to achieve pain relief goals.

SECTION II. OPIOID EXPERIENCED PATIENTS
The Maryland Department of Health (MDH) and the nine Medicaid Managed Care Organizations (MCOs) in Maryland’s HealthChoice Program require Prior Authorization for the following medications:

- Long-acting opioids
- Fentanyl products
- Methadone for pain
- Any opioid prescription (or combination of opioid prescriptions) that results in a patient exceeding 90 morphine milliequivalents (MME) per day. Instructions on calculating MME are available at the CDC website.
For the sake of illustration of what constitutes 90 MME, the following is a list of daily doses of commonly prescribed opioids that equal 90 MME/day:
- Fentanyl 112.5 mcg/day
- Hydrocodone 90 mg/day
- Hydromorphone 22.5 mg/day
- Morphine 90 mg/day
- Oxycodone 60 mg/day
- Oxymorphone 30 mg/day

The following are examples of common prescriptions that equal 90 MME/day:
- oxycodone 20 mg tid
- methadone 20 mg qd
- hydrocodone 10/325, 3 tabs tid

Additionally, some smaller doses of immediate release medications will require prior authorization at less than 90 MME. The decision to limit these medications was made by the Maryland Department of Health in an effort to decrease the number of pills available for diversion. These medications are as follows:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Max per 30 days</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine compounds (all)</td>
<td>1,000</td>
<td>mL</td>
</tr>
<tr>
<td></td>
<td>180</td>
<td>tab/cap</td>
</tr>
<tr>
<td>Hydrocodone compounds (all)</td>
<td>2,750</td>
<td>mL</td>
</tr>
<tr>
<td></td>
<td>180</td>
<td>tab/cap</td>
</tr>
<tr>
<td>Hydromorphone (1 mg/mL solution, 2 mg tablet, 3 mg suppository)</td>
<td>675</td>
<td>mL</td>
</tr>
<tr>
<td></td>
<td>180</td>
<td>tab/supp</td>
</tr>
<tr>
<td>Drug</td>
<td>Amount</td>
<td>Unit</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>--------</td>
<td>------</td>
</tr>
<tr>
<td>Morphine (5 mg suppository, 10 mg/5mL solution, 10 mg suppository)</td>
<td>1,350</td>
<td>mL</td>
</tr>
<tr>
<td></td>
<td>180</td>
<td>supp</td>
</tr>
<tr>
<td>Oxycodone compounds (2.5 mg, 5 mg, 7.5 mg of all formulations)</td>
<td>1,800</td>
<td>mL</td>
</tr>
<tr>
<td></td>
<td>180</td>
<td>tab/cap</td>
</tr>
<tr>
<td>Tramadol (100 mg, 200 mg)</td>
<td>180</td>
<td>tab/cap</td>
</tr>
</tbody>
</table>

In order to receive prior authorization, prescribers must attest to the following:
- Prescriber has reviewed controlled substance prescriptions in a Prescription Drug Monitoring Program (ex: CRISP- Chesapeake Regional Information System for our Patients). For more information about the PDMP, visit the [MDH web site](#).
  If you are not already a registered CRISP user you can register for free on the [CRISP registration web site](#).
- Prescriber will utilize random Urine Drug Screens.
- Prescriber has provided or offered a prescription for naloxone to the patient or patient’s household if the patient has:
  - a history of substance use disorder
  - requires more than 50 MME (for example, more than Fentanyl 62.5 mcg/72 hours, hydrocodone 50 mg/day, hydromorphone 12.5 mg/day, morphine 50 mg/day, oxycodone 33 mg/ day, and oxymorphone 16 mg/day)
  - is prescribed both opioids and benzodiazepines
  - is prescribed other sedative hypnotics
  - or for any other reason deemed clinically appropriate
- Prescriber and patient have signed a Pain Management/Opioid Treatment Agreement/Contract and it is stored in the patient’s medical record.

View the [MDH FAQ on Opioid Prescribing Policies](#).

**Oral Contraceptives**

While some oral contraceptives have additional indications (ex: Beyaz for acne, PMDD, folate replacement; Estrostep Fe for acne; Safyral for folate replacement; ANY OCP on prior authorization requires documentation demonstrating a...
### Natazia
Natazia for heavy periods, most are simply indicated for the prevention of pregnancy.

### Formulary OCPs
compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3 month trial of formulary OCPs]

### Orkambi
**Orkambi**
(lumacaftor/ivacaftor)
Indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient’s genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

**Rx by Pulmonologist**

### Otezla
**Otezla**
(apremilast)
Indicated for:
1. treatment of adult patients with active psoriatic arthritis.
2. treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

**1. Rx by Dermatologist or Rheumatologist**
Failure of at least 1 of the following: methotrexate, plaquenil, Arava, Humira, Embrel

### oxymorphone ER
oxymorphone ER
Indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

**1. Rx by Dermatologist or Rheumatologist**
The Department of Health and Mental Hygiene has mandated that all long-acting opioids require Prior Authorization (PA) as of July 1, 2017. The PA form can be accessed using the following link:

- [OPIOID PRIOR AUTHORIZATION FORM](#)

### Prolia
**Prolia**
(denosumab)
Indicated for:
1. treatment of postmenopausal women with osteoporosis at high risk for fracture.
2. treatment to increase bone mass in men with osteoporosis at high risk for fracture.
3. treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture.
4. treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer.
5. treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

**Rx by Rheumatology or Dermatology**

### Pulmozyme
**Pulmozyme**
(dornase alfa)
Indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

**Rx by Pulmonologist**

### Rasuvo
**Rasuvo**
(methotrexate inj)
Indicated for:
1. Management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy.

**Rx by Rheumatology or Dermatology**
2. Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy.

**Repatha** *(evolocumab)*

**Indicated:**
1. to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
2. as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol.
3. as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

See Prior Authorization protocol on MFC website by clicking link below:

**PRIOR AUTHORIZATION FORM**

To view the most up to date MFC treatment criteria, follow the link below:

**MFC REPATHA PA CRITERIA**

After an initial authorization period of 3 months, an updated lipid panel will be required prior to refill authorization.

**Rituxan Hycela** *(rituximab and hyaluronidase human)*

**Indicated for:**
1. Follicular Lymphoma (FL)
   - Relapsed or refractory, follicular lymphoma as a single agent.
   - Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single agent maintenance therapy.
   - Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
2. Diffuse Large B-cell Lymphoma (DLBCL) previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens.
3. Chronic Lymphocytic Leukemia (CLL) previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC).

Rx by Oncologist

**Rubraca** *(rucaparib)*

**Indicated for:**
1. maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
2. treatment of adult patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies.

Rx by Oncologist
<table>
<thead>
<tr>
<th><strong>Santyl Ointment Collagenase</strong></th>
<th>Indicated for debriding chronic dermal ulcers and severely burned areas.</th>
<th>Rx by Dermatologist or Wound Care Specialist</th>
<th>SANTYL PI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serostim</strong>&lt;br&gt;(somatropin (rDNA origin))</td>
<td>Indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.</td>
<td>Rx by ID or HIV Specialist</td>
<td>SEROSTIM PI</td>
</tr>
<tr>
<td><strong>Seysera</strong>&lt;br&gt;(seracycline)</td>
<td>Indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.</td>
<td>1. Rx by Dermatologist. &lt;br&gt;2. Failure of at least one other oral tetracycline antibiotic.</td>
<td>SEYSERA PI</td>
</tr>
<tr>
<td><strong>Sirturo</strong>&lt;br&gt;(bedaquiline)</td>
<td>Indicated as part of combination therapy in adults with pulmonary multi-drug resistant TB. [Reserved for use when an effective treatment regimen cannot otherwise be provided; not indicated for the treatment of latent, extra pulmonary or drug-sensitive tuberculosis; should be administered by directly observed therapy].</td>
<td>Rx by ID</td>
<td>SITURO PI</td>
</tr>
<tr>
<td><strong>Stimate nasal spray</strong>&lt;br&gt;(desmopressin)</td>
<td>See Desmopressin Products</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stivarga</strong>&lt;br&gt;(regorafenib)</td>
<td>Indicated for: &lt;br&gt;1. treatment of metastatic colorectal cancer, previously treated with ALL the following therapies: &lt;br&gt; a. fluoropyrimidine-based chemotherapy &lt;br&gt; b. oxaliplatin-based chemotherapy &lt;br&gt; c. irinotecan-based chemotherapy &lt;br&gt; d. an anti-vascular endothelial growth factor (VEGF) therapy &lt;br&gt; e. if Kirsten RNA Associated Rat Sarcoma 2 Virus Gene (KRAS) wild type, an anti-epidermal growth factor receptor (EGFR) therapy &lt;br&gt; 2. treatment of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST), previously treated with imatinib mesylate and sunitinib malate. &lt;br&gt; 3. hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.</td>
<td>Rx by Oncologist</td>
<td>STIVARGA PI</td>
</tr>
<tr>
<td><strong>Synagis</strong>&lt;br&gt;(palivizumab)</td>
<td>Indicated for prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.</td>
<td>Please submit: &lt;br&gt;A COMPLETED PRIOR AUTHORIZATION FORM (see link below) via FAX to 410-933-2205</td>
<td>SYNAGIS PI</td>
</tr>
</tbody>
</table>

MedStar Family Choice uses the newest recommendations of the American Academy of Pediatrics (AAP).<br>Recommendations were last updated in the journal Pediatrics (7/28/2014 issue): Updated Guidance for Palivizumab Prophylaxis Among Infants and Young
<table>
<thead>
<tr>
<th>Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection</th>
<th>To view the most up to date AAP Synagis Guidelines, follow the link below: AAP SYNAGIS GUIDELINES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synjardy &amp; Synjardy XR (empagliflozin/metformin)</strong></td>
<td><strong>Indicated:</strong> 1. as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. 2. to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. 1. Rx by Cardiology or Endocrinologist 2. Patients must have known cardiovascular disease to qualify for Synjardy.</td>
</tr>
<tr>
<td><strong>Synribo (omacetaxine)</strong></td>
<td>Indicated to treat adults with chronic phase (CP) or accelerated phase (AP) CML with resistance and/or intolerance to two or more TKIs. Rx by Oncologist</td>
</tr>
<tr>
<td><strong>Tafinlar (dabrafenib)</strong></td>
<td>Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Rx by Oncologist</td>
</tr>
<tr>
<td><strong>Tagrisso (osimertinib)</strong></td>
<td><strong>Indicated:</strong> 1. for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected an FDA-approved test, who have progressed on or after EGFR TKI therapy. 2. in combination with trametinib is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. The use in combination is based on the demonstration of durable response rate. Improvement in disease-related symptoms or overall survival has not been demonstrated for TAFINLAR in combination with trametinib. Rx by Oncologist</td>
</tr>
<tr>
<td><strong>Talzenna (talazoparib)</strong></td>
<td>Indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer. Rx by Oncologist</td>
</tr>
<tr>
<td><strong>Tarceva (erlotinib)</strong></td>
<td>Indicated for: 1. treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. 2. first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine. Rx by Oncologist</td>
</tr>
</tbody>
</table>

July 17, 2019
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indicated for:</th>
<th>Rx by</th>
<th></th>
</tr>
</thead>
</table>
| **Tasigna** (nilotinib) | 1. adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.  
2. adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib.  
3. pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. | Oncologist | **TASIGNA PI** |
| **Tavalisse** (fostamatinib disodium hexahydrate) | 1. Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. | Hematologist | **TAVALISSE PI** |
| **Taytulla** (norethindrone/ethinyl estradiol capsules and ferrous fumarate) | See Oral Contraceptive | | **TAYTULLA PI** |
| **Tibsovo** (ivosidenib) | Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test. | Oncologist | **TIBSOVO PI** |
| **Tykerb** (lapatinib) | **Indicated for:**  
1. the treatment of advanced or metastatic breast cancer, in combination with Xeloda (capecitabine), for patients whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and Herceptin (trastuzumab).  
2. the treatment of postmenopausal women, in combination with letrozole, for hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor when hormonal therapy is indicated. | Oncologist | **TYKERB PI** |
| **Venclexta** (venetoclax) | **Indicated for:**  
1. for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.  
2. In combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. his indication is approved under accelerated approval based on response rates. Continued approval for this | Oncologist | **VENCLEXTA PI** |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Rx by</th>
<th>PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitrakvi (larotrectinib)</td>
<td>Indicated for the treatment of adult and pediatric patients with solid tumors that: • have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, • are metastatic or where surgical resection is likely to result in severe morbidity, and • have no satisfactory alternative treatments or that have progressed following treatment.</td>
<td>Rx by Oncologist</td>
<td>VITRAKVI PI</td>
</tr>
<tr>
<td>Vizimpro (dacomitinib)</td>
<td>Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.</td>
<td>Rx by Oncologist</td>
<td>VIZIMPRO PI</td>
</tr>
<tr>
<td>Xadago (safinamide)</td>
<td>Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease (PD) experiencing “off” episodes.</td>
<td>Rx by Neurologist</td>
<td>XADAGO PI</td>
</tr>
<tr>
<td>Xalkori (crizotinib)</td>
<td>Indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test.</td>
<td>Rx by Oncologist</td>
<td>XALKORI PI</td>
</tr>
<tr>
<td>Xgeva (denosumab)</td>
<td>Indicated for: 1. prevention of skeletal-related events in patients with bone metastases from solid tumors. (does not include multiple myeloma). 2. treatment of adults and skeletally mature adolescents with giant cell tumor of the bone that is unresectable or where surgical resection is likely to result in severe morbidity. 3. treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.</td>
<td>Rx by Oncologist</td>
<td>XGEVA PI</td>
</tr>
<tr>
<td>Xiidra (lifitegrast ophthal)</td>
<td>Indicated for the treatment of the signs and symptoms of dry eye disease.</td>
<td>Must have tried and failed artificial tears.</td>
<td>XIIDRA PI</td>
</tr>
<tr>
<td>Xolair (omalizumab)</td>
<td>Indicated for: 1. moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. 2. chronic idiopathic urticaria in adults and adolescents (12 years of age and above) who remain symptomatic despite H1 antihistamine treatment.</td>
<td>Rx by Allergist or Pulmonologist</td>
<td>XOLAIR PI</td>
</tr>
</tbody>
</table>
| **Xospata**  
| (gilteritinib) | Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. | Rx by Oncologist | XOSPATA PI |
| **Xyrem**  
| (sodium oxybate) | Indicated for:  
1. treatment of cataplexy in narcolepsy.  
2. treatment of excessive daytime sleepiness (EDS) in narcolepsy.  
***Xyrem may only be dispensed to patients enrolled in the Xyrem Success Program | 1. patient > 16 years old  
2. alternative diagnoses must have been excluded  
3. for cataplexy, must have failed tricyclic or SSRIs  
4. for excessive daytime sleepiness, must have failed at least one formulary stimulant treatment (ex: methylphenidate or dextroamphetamine)  
5. initial approval for maximum of 1-month supply with subsequent renewals for maximum approval period of 3 months at a time (Patients are to be re-evaluated by physician no less frequently than every 3 months) | XYREM PI |
| **Yescarta**  
| (axicabtagene ciloleucel) | Indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.  
In accordance with criteria developed by the Maryland Medicaid Program, MedStar Family Choice considers Yescarta (Axicabtagene Ciloleucel) medically necessary when ALL of the following criteria are met:  
1. Recipient is 18 years of age or older; AND  
2. Histologically confirmed diagnosis of one of the following types of aggressive non-Hodgkin’s lymphoma  
   a. Diffuse large B-cell lymphoma (DLBCL), not otherwise specified; or  
   b. High-grade B-cell lymphoma; or  
   c. Primary mediastinal large B-cell lymphoma; or | Rx by Oncologist | YESCARTA PI |
d. Transformed follicular lymphoma; AND
3. Relapsed or refractory disease, when
   a. Recipient has previously received two or more lines of systemic therapy; and
   b. Disease is refractory to the most recent therapy or relapsed within 1 year after autologous hematopoietic stem cell transplantation (HSCT); AND
4. Must have received adequate prior therapy including, at a minimum, all of the following:
   a. An anthracycline-containing chemotherapy regimen; and
   b. For CD20+ disease, anti-CD20 monoclonal antibody; and
   c. For subjects with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DLBCL; AND
5. Documentation of all of the following clinical findings:
   a. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; and
   b. Adequate cardiac, pulmonary, and other organ function (as determined by protocol from treatment facility); AND
6. The treatment facility that dispenses and administers Yescarta is enrolled and complies with the Risk Evaluation and Mitigation Strategy; AND
7. One-time, single administration with dosing in accordance with the FDA label Yescarta (Axicabtagene ciloleucel) is considered investigational and not medically necessary when the above medically necessary criteria are not met, and for all other indications, including but not limited to:
   1. History of malignancy other than nonmelanoma skin cancer or carcinoma in situ (e.g. cervix, bladder, breast) or follicular lymphoma unless disease free for at least 3 years; or
   2. Any central nervous system (CNS) disease, for example, detectable CSF malignant cells, brain metastases, CNS lymphoma, or a history or presence of CNS disorders such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or autoimmune disease with CNS involvement; or
   3. History of allogeneic stem cell transplant, chimeric antigen receptor therapy or other genetically modified T-cell therapy; or
   4. Active, uncontrolled infection; or
   5. Human immunodeficiency virus (HIV); or Hepatitis B or C (if viral load is detectable).

**Zejula (niraparib)**

Indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

Rx by Oncologist

**Zejula (niraparib)**

<table>
<thead>
<tr>
<th>Indicated for:</th>
<th>Rx by Oncologist or Dermatologist</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.</td>
<td>ZELBORAF PI</td>
</tr>
<tr>
<td>2. the treatment of patients with Erdheim Chester Disease with BRAF V600 mutation.</td>
<td></td>
</tr>
</tbody>
</table>

**Zelboraf (vemurafenib)**

Indicated for:

1. palliative treatment of advanced carcinoma of the prostate. (3.6 and 10.8 mg)
2. use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 and 10.8 mg)
3. management of endometriosis. (3.6 mg)

Rx by Oncologist

**Zelboraf (vemurafenib)**

<table>
<thead>
<tr>
<th>Indicated for:</th>
<th>Rx by Oncologist</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. palliative treatment of advanced carcinoma of the prostate. (3.6 and 10.8 mg)</td>
<td>ZOLADEX 3.6 mg PI</td>
</tr>
<tr>
<td>2. use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 and 10.8 mg)</td>
<td></td>
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<tr>
<td>3. management of endometriosis. (3.6 mg)</td>
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</tbody>
</table>

**Zoladex (goserelin)**

Indicated for:

1. palliative treatment of advanced carcinoma of the prostate. (3.6 and 10.8 mg)
2. use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 and 10.8 mg)
3. management of endometriosis. (3.6 mg)

Rx by Oncologist

**Zoladex (goserelin)**

<table>
<thead>
<tr>
<th>Indicated for:</th>
<th>Rx by Oncologist</th>
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</thead>
<tbody>
<tr>
<td>1. palliative treatment of advanced carcinoma of the prostate. (3.6 and 10.8 mg)</td>
<td>ZOLADEX 3.6 mg PI</td>
</tr>
<tr>
<td>2. use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 and 10.8 mg)</td>
<td></td>
</tr>
<tr>
<td>3. management of endometriosis. (3.6 mg)</td>
<td></td>
</tr>
</tbody>
</table>
4. palliative treatment of advanced breast cancer in pre- and peri-menopausal women. (3.6 mg)
5. use as an agent to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (3.6 mg)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Prescription</th>
<th>PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zontivity (vorapaxar)</td>
<td>Indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD).</td>
<td>Rx by Cardiology, Neurology or Vascular Surgery</td>
<td>ZONTIVITY PI</td>
</tr>
<tr>
<td>Zurampic (lesinurad)</td>
<td>Indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.</td>
<td>Rx by Rheumatologist</td>
<td>ZURAMPIC PI</td>
</tr>
<tr>
<td>Zydelig (idelalisib)</td>
<td>Indicated for: 1. treatment of patients with relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. 2. treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies. 3. treatment of patients with relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.</td>
<td>Rx by Oncologist</td>
<td>ZYDELIG PI</td>
</tr>
<tr>
<td>Zykadia (ceritinib)</td>
<td>Indicated for the treatment of adults with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase-positive as detected by an FDA-approved test.</td>
<td>Rx by Oncologist</td>
<td>ZYKADIA PI</td>
</tr>
</tbody>
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