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To: MaineCare Providers

From: Jill Kingsbury, Director of Pharmacy

Date: February 4, 2020

Re: PDL Update for **02/07/2020**

MaineCare RX Portal: Reminder

The MaineCare Rx Portal https://providerportal.megov.changehealthcare.com/mepp/report/index.joi is a MaineCare web application for providers to electronically search and review drug status on the MaineCare Preferred Drug List (PDL), review MaineCare Prior Authorization (PA) requirements and submit PA's electronically. Access to the MaineCare Rx Portal requires registration; prescribers, pharmacists, and members will have to self register prior to accessing information. Once the registration process is complete, depending on role type, the user will have web based access to the MaineCare PDL.

The following medication(s) have been recently added/changed to the MaineCare PDL as non-preferred and will require prior authorization.

Duaklir Pressair	Katerzia	Mvasi	Minolira ER	Rinvoq	Rybelsus
Slynd	Tosymra				

The following medication(s) have been recently added/changed to the MaineCare PDL as preferred and will *not* require prior authorization. This is a correction to a previous announcement. The correct labeler is listed below.

Pimecrolimus Cream is (Auth Generic labeler 68682) Oceanside Pharmaceuticals.

The following medication(s) have been recently added to the MaineCare PDL as well as new PDL criteria:

Methylphenidate Er Tabs (Generic Concerta labeler 10147) Patriot Pharmaceuticals and brand name C**oncerta** moved back to preferred with generic labeler 10147 to assist in transition.

Adhansia XR will be non-preferred and products must be used in specified step order. For the treatment of patients ≥ 6 years of age.

Aklief will be non-preferred and is recommended for the treatment of patients ≥ 9 years of age.

Beser Lotion will be non-preferred and is recommended for the treatment of patients ≥ 12 years of age.

Drizalma sprinkles will be non-preferred with a DDI: Drizalma Sprinkle avoid the concomitant use of duloxetine with potent CYP1A2 inhibitors (e.g. fluvoxamine, cimetidine, ciprofloxacin, enoxacin).

Ezallor Sprinkles will be non-preferred and is recommended for the treatment of patients ≥ 18 years of age.

Gvoke will be non-preferred and is recommended for the treatment of patients ≥ 2 years of age.

Rozlytrek will be non-preferred and will be considered for the treatment of: Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive OR Adult and pediatric patients 12 years of age and older with solid tumors that: Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation AND Are metastatic or where surgical resection is likely to result in severe morbidity, AND Have either progressed following treatment or have no satisfactory alternative therapy. With a DDI: QTc interval prolongation can occur with Rozlytrek®. Avoid the concomitant use of Rozlytrek® with other products with a known potential to prolong QT/QTc interval.

Inrebic will be non-preferred and will be considered for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

Kalydeko will be non-preferred and will be considered for patients with cystic fibrosis (CF) aged 6 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation 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 mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

Kanjinti will be non-preferred and the PA will be required to confirm FDA approved indication.

Nayzilam will be non-preferred with a quantity limit of 5/month and a DDI: Avoid concomitant use of Nayzilam® with moderate or strong CYP3A inhibitors.

Nourianz will be non-preferred and have a DDI: Avoid use of Nourianz® with strong CYP3A4 inducers (e.g. carbamazepine, rifampin, phenytoin, St. John's wort).

Proair Digihaler will be non-preferred and is recommended for the treatment of patients ≥ 4 years of age.

Spinraza will be non-preferred and the updated clinical criteria is listed below.
The diagnosis is spinal muscular atrophy (SMA) type 1, 2, or 3 (results of genetic testing must be submitted) AND
The patient has at least 2 copies of the SMN2 gene AND
The prescriber is a neurologist, pulmonologist, or other physician with expertise in treating SMA
Baseline motor ability has been established using one of the following exams:

- Hammersmith Infant Neurological Exam (HINE)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module Test (non-ambulatory)

Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) AND
Prior to starting therapy, and prior to each dose, the following laboratory tests will be conducted:

- Treating provider attests the member has a platelet count > 50,000/ml or greater
- Treating provider agrees to do platelet count and coagulation test before each dose
- Treating provider agrees to do a quantitative spot urine protein test before each dose

Concomitant use of Spinraza and Zolgensma is investigational and will not be approved AND Use of Spinraza after gene replacement therapy, including Zolgensma is investigational and will not be approved. Note: Initial approval will be granted for 4 loading doses (the first 3 loading doses should be administered at 14-day intervals; the 4th loading dose should be administered 30 days after the 3rd dose). Renewal may be granted for up to 12 months with a maximum of 3 doses approved per year (12mg (5ml) every 4 months). For therapy continuation, clinical documentation must be submitted documenting improvement or maintenance of motor ability OR slower progression of disease than would otherwise be expected.

Spravato will be non-preferred and needs to be administered in an equipped and accredited conscious sedation facility or department. Psychiatry recommended. Please see the definition of conscious sedation.

1. Pre-procedure patient evaluation and preparation
    - Medical records review
    - Underlying medical issues
    - Preparation of the patient
    - Pre-procedure instruction, medication usage, counseling, fasting
2. Patient Monitoring
    - Level of consciousness (responsiveness)
    - Breathing/ventilation
    - Oxygenation
    - Pulse oximetry-continuous monitoring with alarm capability
    - Hemodynamic monitoring
    - Contemporaneous recording of at least HR and oximetry with frequent BP monitoring that is automated or individual able to measure BP frequently (e.g. every 5-10 min) during period of sedation.
    - Presence of individual dedicated to patient monitoring during period of sedation
3. Supplemental oxygen available
4. Emergency support
    - Presence of individual(s) capable of establishing a patent airway (i.e. advanced life-support skills)
    - Presence of emergency and airway equipment
    - Includes suction, airway adjunct such as bag-valve mask and oral and nasal airways
    - Presence of individual to establish intravenous access
5. Recovery Care
    - Observe and monitor patients in appropriately staffed and equipped area until near baseline level of consciousness and are no longer at risk for cardiorespiratory depression
    - Monitor oxygenation continuously until patients are no longer at risk for hypoxemia.
    - Monitor ventilation and circulation at regular intervals
    - Design discharge criteria to minimize risk of CNS or cardiorespiratory depression after discharge from observation by trained personnel

Symdeko will be non-preferred and will be considered for patients with cystic fibrosis (CF) aged 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

Tovet Foam will be non-preferred and is recommended for the treatment of patients ≥ 9 years of age.

Trikafta will be non-preferred and will be considered for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation.

Vyndamax will be non-preferred and a PA will be required to confirm FDA approved indication. Vyndamax will be considered for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

Xembify will be non-preferred and is indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older.

Xenleta will be non-preferred and will be considered for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Hemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

Zulresso will be non-preferred and is recommended for the treatment of patients ≥ 18 years of age. Zulresso® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Zulresso® REMS.