

## Pharmacy Policy and Formulary Update Effective October 1, 2009

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### Select Biologic Chemotherapy Agents

This policy was recently reviewed and now states that KRAS mutation testing must be performed and the results documented in the patients' medical records prior to the use of cetuximab and panitumumab. Testing must be done at an MVP-participating laboratory, preferably an independent clinical laboratory like Quest Diagnostics. Quest Diagnostics is MVP's national participating laboratory. Contact your Professional Relations representative for a list of other MVP-participating laboratories in your geographic region who perform this test.

### Tamiflu & Relenza

These medications have been moved to formulary, Tier 2 on an interim basis. MVP will continue to monitor utilization.

### Policy Updates Effective Oct. 1, 2009

#### Aldosterone Blockers (Inspra<sup>®</sup>)

- Policy approved for archive due to appropriate utilization

#### ACE/ARB

- Exforge HCT<sup>®</sup> was added to the policy requiring failure on an ACE inhibitor first

#### Infusion Medications for MS (Tysabri<sup>®</sup>)

- Definitions for the various forms of multiple sclerosis were removed
- Language was added stating that "alternative treatment criteria for members currently with high disease activity, as defined by a high number of relapses while on treatment and the progression of gadolinium-positive lesions on MRI, will be reviewed on a case-by-case basis"

#### Orphan Drug

- Prior authorization will no longer be required for Velcade<sup>®</sup>
- Arcalyst<sup>®</sup>, Cinryze<sup>®</sup> and Adagen<sup>®</sup> were added to the policy and will require prior authorization
- Kuvan<sup>®</sup> was removed from this policy. Refer to new Kuvan policy

#### Mail Order

- Excluded drugs by therapeutic class were updated
- Language was added stating that the exceptions list is not all inclusive and to refer to the MVP Formulary for the most up-to-date information

#### Acthar<sup>®</sup>

- New policy
- Prior authorization is required for FDA approved indications based on the following criteria:

- Medical contraindication or significant intolerance to corticosteroids
- Indication is steroid-responsive
- All other standard of care medical treatments have been tried and failed or are contraindicated or significant intolerance is documented. This includes the failure or contraindication of cosyntropin in diagnosing adrenal insufficiency
- Prior authorization is required when used to treat infantile spasms when the following criteria are met:
  - Documentation supporting diagnosis of infantile spasms including onset of age, description of symptoms, and results of EEG identifying hypsarrhythmia or modified hypsarrhythmia must be submitted
  - Treatment plan and goals must be submitted
  - Dose, frequency, and number of requested vials per month must be submitted

### **Kuvan®**

- New policy
- Prior authorization is required based on the following criteria:
  - Diagnosis of phenylketonuria and current and prior phenylalanine levels are above the upper limit of the recommended ranges
  - Failed phenylalanine-restricted diet despite compliance

### **Thrombopoiesis-stimulating Proteins**

- New policy
- Prior authorization is required for Nplate® and Promacta® based on the following criteria:
  - Diagnosis of chronic immune idiopathic thrombocytopenia purpura
  - Platelet count less than 30,000/microliter
  - ALT levels less than 3X upper limit of normal
  - Serum alanine aminotransferase, aspartate aminotransferase and bilirubin prior to initiation of Promacta®, every 2 weeks during the dose-adjustment phase and monthly following establishment of a stable dose
  - Monitoring per prescribing information
  - Failure or contraindication to IVIG, corticosteroids and immunoglobulins
  - Failure or contraindication to a splenectomy
  - Degree of thrombocytopenia and clinical condition puts member at increase risk of bleeding
  - Greater than 18 years old
  - Target platelet count of 50,000/microliter
  - Must be ordered by a hematologist
  - Documentation provided regarding outcome and length of previous therapies such as IVIG, corticosteroids, cytotoxic therapies, danazol, azathioprine, and splenectomy
- Policy also includes criteria required for continuation of therapy

### **Mozobil®**

- New policy
- Prior authorization is required based on the following criteria:
  - Bone marrow biopsy, and/or radiologic reports confirming diagnosis of non-Hodgkin's lymphoma or multiple myeloma

- Undergoing peripheral blood collection for hematopoietic stem cell transplantation
- Patient is 18 years of age and older
- Must be ordered by an oncologist or hematologist
- GCSF will be administered for 4 days prior to the first dose of Mozobil<sup>®</sup>
- Used in combination with GCSF as directed in the package label
- Failure of GCSF at 10 micrograms/kg for at least 4 days

**The following policies were reviewed and approved with no changes to criteria:**

- Tekturna/HCT (Direct Renin Inhibitors)

**Medications removed from prior authorization**

Banzel<sup>®</sup> no longer requires prior authorization and is non-formulary, Tier 3.

**Medication Recalls and Withdrawals**

In the past several weeks, the Food and Drug Administration (FDA) has issued important medication warnings, withdrawals, and requests for product labeling changes. Highlights of FDA activities include:

- On July 7, 2009, FDA notified health care professionals that it is taking several actions to reduce the risk of overdose in patients using pain medications containing propoxyphene because of data linking propoxyphene and fatal overdoses. The agency will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products and to provide a medication guide to patients stressing the importance of using the drugs as directed. The FDA is also requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action.

**Formulary Updates for Commercial Members**

The MVP Formulary is updated after each Pharmacy and Therapeutics Committee meeting. The most current version is available online at [www.mvphealthcare.com](http://www.mvphealthcare.com). Simply go to the *Provider* section of the site and under *Pharmacy*, click on *Formulary*. The MVP Formulary can be downloaded to a PDA device from [www.epocrates.com](http://www.epocrates.com). There is a link to ePocrates<sup>®</sup> on the MVP Web site. Please update your ePocrates account if your computer or PDA is set up to automatically download the Formulary. Unless otherwise noted, the following Formulary information is effective Oct. 1, 2009.

**New Drugs**

*(recently approved by the FDA, prior authorization required, Tier 3)*

Multaq <sup>®</sup>	Ilaris <sup>®</sup>
Ulesfia <sup>®</sup>	Zipsor <sup>™</sup>
Cambia <sup>™</sup>	Ozurdex <sup>™</sup>
Caldolor <sup>™</sup> (medical benefit)	

**Drugs Added to Formulary (Tier 1)**

sulfacetamide topical 10% (generic Klaron<sup>®</sup>)  
malathione lotion (generic Ovide<sup>®</sup>)

## Medications Removed from Prior Authorization

Banzel<sup>®</sup>

### 2009 Formulary Updates for Medicare Part D Members

The following are recent updates to the Medicare Part D Formulary. For a more detailed document, visit [https://www.mvphealthcare.com/medicare/documents/2009\\_formulary\\_changes.pdf](https://www.mvphealthcare.com/medicare/documents/2009_formulary_changes.pdf).

In addition, a list of medications that require prior authorization or are subject to step therapy or quantity limits and corresponding Medicare Part D policies can be found at <https://www.mvphealthcare.com/medicare/2009MedicarePARTDPAlist.html>.

### Drugs Added to Formulary

#### Tier 1

topiramate

mycophenolate<sup>#</sup> 250mg

ursodiol

risperidone ODT

carbamazepine ext-rel

sulfacetamide topical 10%

#### Tier 2

Banzel<sup>®</sup>

Degarelix<sup>®#</sup> 80mg

Vimpat<sup>®</sup>

Exforge HCT<sup>®#</sup>

Lamictal ODT<sup>®</sup>

Creon<sup>®</sup>

#### Tier 3

mycophenolate<sup>#</sup> 500mg

Xenazine<sup>®#</sup>

Afinitor<sup>®#</sup>

Promacta<sup>®#</sup>

Degarelix<sup>®</sup> 120mg

Cimzia<sup>®#</sup>

*<sup>#</sup> subject to prior authorization, step therapy or quantity limits*

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