This program applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Health Insurance Marketplace and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard prior authorization program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

Program specific denial language for prerequisite step therapy component does not apply. Instead, supplemental program denial language will apply.

### FDA APPROVED INDICATIONS AND DOSAGE

<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication</th>
<th>Dosage</th>
</tr>
</thead>
</table>
| **Rayos®** (prednisone delayed-release tablet) | • as an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal, respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation | • Initial dose: Rayos 5 mg administered once per day. Patients currently on immediate-release prednisone, prednisolone, or methylprednisolone should be switched to Rayos at an equivalent dose based on relative potency.  
• Maintenance dose: Use lowest dosage that will maintain an adequate clinical response.  
• Discontinuation: Withdraw gradually in discontinuing long-term or high-dose therapy.  
• Rayos should be taken daily with food.  
• Rayos should be swallowed whole and not broken, divided, or chewed.  |
|                           | • for the treatment of certain endocrine conditions                           |                                                                                                                                         |
|                           | • and for palliation of certain neoplastic conditions                          |                                                                                                                                         |

**CLINICAL RATIONALE**

Rayos (prednisone delayed release) is indicated in the treatment of the following diseases and conditions:

- **Allergic Conditions**
  - Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in adults and pediatric populations with:
    - Atopic dermatitis
    - Drug hypersensitivity reactions
    - Seasonal or perennial allergic rhinitis
    - Serum sickness

- **Dermatologic Diseases**
  - Bullous dermatitis herpetiformis
• Contact dermatitis
• Exfoliative erythroderma
• Mycosis fungoides
• Pemphigus
• Severe erythema multiforme (Stevens-Johnson syndrome)

• Endocrine Conditions
  • Congenital adrenal hyperplasia
  • Hypercalcemia of malignancy
  • Nonsuppurative thyroiditis
  • Primary or secondary adrenocortical insufficiency: hydrocortisone or cortisone is the first choice: synthetic analogs may be used in conjunction with mineralocorticoids where applicable

• Gastrointestinal Diseases
  • During acute episodes in:
    ▪ Crohn’s Disease
    ▪ Ulcerative colitis

• Hematologic Diseases
  • Acquired (autoimmune) hemolytic anemia
  • Diamond-Blackfan anemia
  • Idiopathic thrombocytopenic purpura in adults
  • Pure red cell aplasia
  • Secondary thrombocytopenia in adults

• Neoplastic Conditions
  • For the treatment of:
    ▪ Acute leukemia
    ▪ Aggressive lymphomas

• Nervous System Conditions
  • Acute exacerbations of multiple sclerosis
  • Cerebral edema associated with primary or metastatic brain tumor, craniotomy or head injury

• Ophthalmic Conditions
  • Sympathetic ophthalmia
  • Uveitis and ocular inflammatory conditions unresponsive to topical steroids

• Conditions Related to Organ Transplantation
  • Acute or chronic solid organ rejection

• Pulmonary Diseases
  • Acute exacerbations of chronic obstructive pulmonary disease (COPD)
  • Allergic bronchopulmonary aspergillosis
  • Aspiration pneumonitis
  • Asthma
  • Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate chemotherapy
  • Hypersensitivity pneumonitis
  • Idiopathic bronchiolitis obliterans with organizing pneumonia
  • Idiopathic eosinophilic pneumonias
  • Idiopathic pulmonary fibrosis
- Pneumocystis carinii pneumonia (PCP) associated with hypoxemia occurring in an HIV(+) individual who is also under treatment with appropriate anti-PCP antibiotics.
- Symptomatic sarcoidosis

Renal Conditions
- To induce a diuresis or remission of proteinuria in nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus

Rheumatologic Conditions
- As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
  - Acute gouty arthritis
- During an exacerbation or as maintenance therapy in selected cases of:
  - Ankylosing spondylitis
  - Dermatomyositis/polymyositis
  - Polymyalgia rheumatica
  - Psoriatic arthritis
  - Relapsing polychondritis
  - Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low dose maintenance therapy)
  - Sjogren's syndrome
  - Systemic lupus erythematosus
  - Vasculitis

Specific Infectious Diseases
- Trichinosis with neurologic or myocardial involvement.
- Tuberculous meningitis with subarachnoid block or impending block used concurrently with appropriate anti-tuberculous chemotherapy.

Rayos should follow individualized dosing based on disease severity and patient response. The timing of administration should take into account the delayed-release pharmacokinetics and the disease or condition be treated. The recommended initial dose of Rayos is between 5-60 mg once per day depending on disease state. Patients currently on immediate-release prednisone, prednisolone, or methylprednisolone should be switched to Rayos at an equivalent dose based on relative potency (see below). Rayos should be maintained at the lowest dose which provides adequate clinical response. Withdraw Rayos gradually if discontinuing long-term or high-dose therapy.

Rayos 5 mg dosage equivalency:
- Betamethasone 0.75 mg
- Paramethasone 2 mg
- Cortisone 25 mg
- Prednisolone 5 mg
- Dexamethasone 0.75 mg
- Prednisone 5 mg
- Hydrocortisone 20 mg
- Triamcinolone 4 mg
- Methylprednisolone 4 mg

Safety¹
Rayos is contraindicated in patients who have known hypersensitivity to prednisone or to any of the excipients. Rare instances of anaphylaxis have occurred in patients receiving corticosteroid therapy.

REFERENCES
Rayos Prior Authorization

TARGET AGENTS

Rayos (prednisone delayed release tablet)

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
</tr>
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<tbody>
<tr>
<td>Rayos (prednisolone delayed release tablet)</td>
<td></td>
<td></td>
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<tr>
<td>1 mg oral tablet</td>
<td>22100045000610</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>2 mg oral tablet</td>
<td>22100045000620</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>3 mg oral tablet</td>
<td>22100045000630</td>
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PRIOR AUTHORIZATION THERAPY CRITERIA FOR APPROVAL

Target Agent will be approved when ALL of the following are met:

1. The patient has an FDA labeled indication for the requested agent AND

2. ONE of the following
   a. The patient has tried and had an inadequate response to BOTH a generic oral prednisone AND at least 1 other different generic oral corticosteroid (e.g., dexamethasone, methylprednisolone, prednisolone) OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL generic oral corticosteroids that would NOT be expected to occur with the requested agent AND

3. The patient does not have an FDA labeled contraindication to the requested agent

Length of Approval: 6 months

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Step Therapy Supplement

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Please note, this does not include or apply to quantity limit questions.

STEP THERAPY SUPPLEMENT

OBJECTIVE
The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

CONDITIONS FOR APPROVAL
The requested agent will be approved when ONE of the following are met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   a. A statement by the prescriber that the patient is currently taking the requested agent
   AND
   b. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
   AND
   c. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   OR

2. The patient’s medication history include the required prerequisite/preferred agent(s) as indicated by:
   a. Evidence of a paid claim(s) within the past 999 days
   OR
   b. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event

   OR

3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: As per program specific criteria