Rayos Prior Authorization Criteria

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

This is a FlexRx Standard and GenRx Standard program.

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

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indications
Rayos® (prednisone delayed-release) Oral tablet	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 ▪ 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: 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

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE[1]

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
- Cortisone 25 mg
- Dexamethasone 0.75 mg
- Hydrocortisone 20 mg
- Methylprednisolone 4 mg
- Paramethasone 2 mg
- Prednisolone 5 mg
- Prednisone 5 mg
- Triamcinolone 4 mg

Safety[1]

Rayos is contraindicated in patients who have known hypersensitivity to prednisone or to any of the excipients.

REFERENCES

1. Rayos prescribing information. Horizon Pharma USA, Inc. March 2021.

Rayos Prior Authorization

TARGET AGENTS

Rayos (prednisone delayed release tablet)

Brand (generic)	GPI	Multisource Code
Rayos (prednisone delayed release tablet)		
1 mg oral tablet	22100045000610	M, N, O, or Y
2 mg oral tablet	22100045000620	M, N, O, or Y
5 mg oral tablet	22100045000630	M, N, O, or Y

PRIOR AUTHORIZATION THERAPY CRITERIA FOR APPROVAL

Evaluation

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. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent
      OR
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication
   AND
3. 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 an intolerance or hypersensitivity to BOTH a generic oral prednisone AND at least 1 other different generic oral corticosteroid that would NOT be expected to occur with the requested agent
      OR
   C. The patient has an FDA labeled contraindication to ALL generic oral corticosteroids that would NOT be expected to occur with the requested agent
      OR
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      i. A statement by the prescriber that the patient is currently taking the requested agent
         AND
      ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
         AND
      iii. The prescriber states that a change in therapy is expected to be ineffective or cause harm
      OR
   E. The prescriber has provided documentation that ALL generic oral corticosteroids 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
   AND
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months