FDA APPROVED INDICATIONS AND DOSAGE

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<th>Agent</th>
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<th>Dosage</th>
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| 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  
• for the treatment of certain endocrine conditions  
• and for palliation of certain neoplastic conditions | • 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. |

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 antituberculous 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

**Safety**
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

OBJECTIVE
The intent of the Rayos prior authorization is to encourage appropriate use, the use of more cost-effective products over the more expensive Rayos product, and to accommodate for the use of Rayos when a patient has a FDA contraindication, hypersensitivity, or intolerance to at least 2 different cost-effective products. The PA defines appropriate use as a diagnosis consistent with product labeling. Requests for Rayos will be reviewed when patient-specific documentation has been provided. Approval will not be granted for patients who have a contraindication to Rayos.

TARGET AGENTS
Rayos (prednisone delayed release tablet)

PRIOR AUTHORIZATION THERAPY CRITERIA FOR APPROVAL
Rayos will be approved when ONE of the following is met:

1. The patient has a diagnosis for an FDA labeled indication to the requested agent AND
2. The patient does not have a FDA labeled contraindication to the requested agent AND
3. ONE of the following
   a. The patient medical history includes trial and failure of generic prednisone and at least 1 other different generic oral corticosteroid OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least 2 different generic oral corticosteroids

Length of Approval: 6 months

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| FDA Labeled Contraindication | Hypersensitivity to prednisone or any excipients |