Clinical Policy: Prednisone Delayed-Release (Rayos)

Reference Number: CP.CPA.273
Effective Date: 11.16.16
Last Review Date: 11.19
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Delayed-release prednisone (Rayos®) is a corticosteroid.

FDA Approved Indication(s)

Rayos is indicated:

- 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
- For palliation of certain neoplastic conditions

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Rayos is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. All FDA-Approved Indications (must meet all)**:**

1. Prescribed for one of the following conditions:
   a. Allergic (atopic dermatitis, drug hypersensitivity reactions, seasonal or perennial allergic rhinitis, serum sickness);
   b. Dermatologic (bullous dermatitis herpetiformis, contact dermatitis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome));
   c. Endocrine (congenital adrenal hyperplasia, hypercalcemia of malignancy, nonsuppurative thyroiditis, primary or secondary adrenocortical insufficiency);
   d. Gastrointestinal (Crohn's Disease, ulcerative colitis);
   e. Hematologic (acquired (autoimmune) hemolytic anemia, Diamond-Blackfan anemia, idiopathic thrombocytopenic purpura in adults, pure red cell aplasia, secondary thrombocytopenia in adults);
   f. Neoplastic (acute leukemia, aggressive lymphomas);
   g. Nervous system (acute exacerbations of multiple sclerosis, cerebral edema associated with primary or metastatic brain tumor, craniotomy or head injury);
   h. Ophthalmic (sympathetic ophthalmia, uveitis and ocular inflammatory conditions unresponsive to topical steroids);

i. Acute or chronic solid organ rejection;
j. Pulmonary (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 human immunodeficiency virus (HIV)-positive individual who is also under treatment with appropriate anti-PCP antibiotics);
k. Renal (to induce a diuresis or remission of proteinuria in nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus);
l. Rheumatologic (acute gouty arthritis, exacerbation or maintenance therapy in cases of ankylosing spondylitis, dermatomyositis/polymyositis, polymyalgia rheumatica, psoriatic arthritis, relapsing polychondritis, rheumatoid arthritis (including juvenile rheumatoid arthritis), Sjogren's syndrome, systemic lupus erythematosus, vasculitis);
m. Infectious diseases (Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block);

2. Documentation supports inability to use generic immediate-release oral prednisone due to contraindications or intolerance to excipients.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

A. All FDA-Approved Indications (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: Length of Benefit

B. Other diagnoses/indications(must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key:

COPD: chronic obstructive pulmonary disease
DMARD: disease-modifying anti-rheumatic drug
FDA: Food and Drug Administration
HIV: human immunodeficiency virus
PCP: pneumocystis carinii pneumonia

Appendix B: Therapeutic Alternatives:
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
prednisone	Varies based on condition being treated	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to prednisone or any excipients in the formulation
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
All FDA-approved indications	Patients on immediate-release prednisone, prednisolone, or methylprednisolone should be switched to Rayos at an equivalent dose based on relative potency Initial dose: 5 mg PO QD Maintenance dose: Use lowest dosage that will maintain an adequate clinical response.	Varies

VI. Product Availability

Delayed-release tablets: 1 mg, 2 mg, and 5 mg

VII. References

1. Rayos Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; September 2017. Available at: www. Rayosrx.com. Accessed August 13, 2019.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 13, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	06.01.17	11.17
4Q 2018 annual review: no significant changes; removed the requirement for concomitant DMARD therapy as this is not readily enforceable; references reviewed and updated.	07.16.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.13.19	11.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.