

Pharmacy Policy Bulletin

Title: Prednisone delayed release (Rayos®)

Policy #: Rx.01.191

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ **Intent:**

The intent of this policy is to communicate the medical necessity criteria for prednisone delayed release (Rayos®) as provided under the member's prescription drug benefit.

▶ **Description:**

Prednisone is a synthetic adrenocortical steroid with predominantly corticosteroid properties and slight mineralocorticoid activity. The pharmacological effects due to prednisone's corticosteroid properties include: promotion of gluconeogenesis; increased deposition of glycogen in the liver; inhibition of the utilization of glucose; anti-insulin activity; increased catabolism of protein; increased lipolysis; stimulation of fat synthesis and storage; increased glomerular filtration rate and resulting increase in urinary excretion of urate (creatinine excretion remains unchanged); and increased calcium excretion. Additionally, prednisone depresses production of eosinophils and lymphocytes, while increasing erythropoiesis and production of polymorphonuclear cells, and inhibits inflammatory processes. Sodium retention and hypertension are related to the mineralocorticoid activity. Prednisone use may lead to suppression of corticotropin production with subsequent suppression of endogenous corticosteroids.

Delayed release prednisone (Rayos®) differs from immediate release prednisone only in its lag time for release, which is approximately 4 hours after oral ingestion when taken with food. The other pharmacokinetic parameters of absorption, distribution, and elimination are comparable to immediate release prednisone.

▶ **Policy:**

Prednisone delayed release (Rayos®) is approved when ALL of the following are met:

1. Diagnosis of an FDA approved indication
2. Member's condition requires the use of long term prednisone
3. Inadequate response or inability to tolerate one immediate-release oral steroid

▶ **Black Box Warning:**

N/A

▶ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION


Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ **References:**

Rayos® (prednisone delayed release) [package insert]. Lake Forest, IL. Horizon Pharma USA, Inc. September 2017. Available at:

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=281ab967-7565-4bef-9c0c-a646589c671e&type=display#section-11.1>. Accessed November 12, 2018.

▶ **Applicable Drugs:**

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand name	Generic name
Rayos®	prednisone delayed release

▶ **Cross References:**

N/A

Policy Version Number:	3.00
P&T Approval Date:	October 11, 2018
Policy Effective Date:	January 1, 2019
Next Required Review Date:	October 11, 2019

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.