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5.30.013

Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Endocrine and Metabolic Agents	**Original Policy Date:**	March 13, 2015
Subject:	Rayos	**Page:**	1 of 5

Last Review Date: September 19, 2025

Rayos

Description

Rayos (prednisone)

Background
Rayos is a delayed-release prednisone used to treat pain and inflammation associated with certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal, respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation. It is also used for the treatment of certain endocrine conditions and for palliation of certain neoplastic conditions. Rayos resembles the naturally occurring adrenocorticoids, which are important in anti-inflammatory responses, metabolism, and other hormone responses. Rayos is designed to release the active metabolite beginning approximately 4 hours after intake. Taking Rayos at bedtime can result in decreased morning stiffness in patients with rheumatoid arthritis (1).

Regulatory Status
FDA-approved indications: Rayos is a corticosteroid 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 and for palliation of certain neoplastic conditions (1).

The use of Rayos may increase risks for conditions related to corticosteroid therapy which include Cushing’s syndrome and hyperglycemia, especially with chronic use; therefore, doses should be tapered gradually for withdrawal after chronic use (1).

Rayos may cause immunosuppression and increased risk for developing infections, reactivation of latent infections, and masking of infective symptoms. Rayos is not recommended in patients with active, severe infections until the infections are controlled (1).

Patients taking Rayos may also experience elevated blood pressure, hyperglycemia, salt and water retention, and hypokalemia, hence blood pressure, glucose levels, sodium, potassium serum levels should be monitored (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rayos may be considered **medically necessary** if the conditions indicated below are met.

Rayos may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Allergic Condition
2. Dermatologic Disease
3. Endocrine Condition
4. Gastrointestinal Disease
5. Hematologic Disease
6. Neoplastic Condition
7. Nervous System Condition
8. Ophthalmic Condition
9. Conditions Related to Organ Transplantation
10. Pulmonary Disease
11. Renal Condition

12. Rheumatologic Condition

AND ALL of the following:

1. Patient has had an inadequate treatment response or intolerance to immediate release prednisone
2. Patient has had an inadequate treatment response, intolerance, or contraindication to at least **TWO** of the following oral corticosteroids:
    a. Dexamethasone
    b. Hydrocortisone
    c. Methylprednisolone

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Allergic Condition
2. Dermatologic Disease
3. Endocrine Condition
4. Gastrointestinal Disease
5. Hematologic Disease
6. Neoplastic Condition
7. Nervous System Condition
8. Ophthalmic Condition
9. Conditions Related to Organ Transplantation
10. Pulmonary Disease
11. Renal Condition
12. Rheumatologic Condition

AND the following:

1. Patient has improved or stabilized on therapy

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Rayos is a delayed-release prednisone used to treat pain and inflammation associated with certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal, respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation. It is also used for the treatment of certain endocrine conditions and for palliation of certain neoplastic conditions. The use of Rayos may increase risks for conditions related to corticosteroid therapy which include Cushing's syndrome and hyperglycemia. The use of Rayos may result in immunosuppression and increases risk for developing infections. Patients taking Rayos may also experience elevated blood pressure, salt and water retention, and hypokalemia, hence blood pressure, sodium, potassium serum levels should be monitored (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rayos while maintaining optimal therapeutic outcomes.

References

1. Rayos [package insert]. Lake Forest, IL: Horizon Pharma USA, Inc.; March 2021.

Policy History

Date	Action
March 2015	New policy addition
	Annual editorial review and reference update
September 2016	Annual editorial review
	Policy number change from 5.07.13 to 5.30.13
December 2017	Annual review and reference update
November 2018	Annual editorial review and reference update
December 2019	Annual review
December 2020	Annual review and reference update

March 2021	Addition of requirement for inadequate response, intolerance, or contraindication to two oral corticosteroids; changed the continuation PA duration from 12 months to 6 months per MQA.
June 2021	Annual review
June 2022	Annual review and reference update
September 2023	Annual review. Changed policy number to 5.30.013
June 2024	Annual review
September 2024	Annual review
September 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.