Rayos (prednisone)

Background
Rayos is delayed-release prednisone used to treat rheumatological diseases that affects the joints and connective tissues to lessen the pain and inflammation associated with those conditions. The drug resembles the naturally occurring adrenocorticoids, which are important in anti-inflammatory responses, metabolism, and other hormone responses. Since Rayos is delayed-release medication it allows for a 4 hour delayed effect, which allows patients to take at bedtime for deceased morning stiffness due to rheumatological disease (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** for the treatment 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; and 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 ONE of the following:
1. An intolerance to immediate release prednisone
2. Treatment failure after a trial of immediate release prednisone

**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**

**Duration**  12 months
Rationale

Summary
Rayos is delayed-release prednisone used to treat rheumatological diseases that affect the joints and connective tissues to lessen the pain and inflammation associated with those 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

Policy History

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<td>March 2015</td>
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<tr>
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<td>Annual editorial review and reference update</td>
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<td>September 2016</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.