

5.30.13

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| Section: | Prescription Drugs | Effective Date: | July 1, 2022 |
| Subsection: | Endocrine and Metabolic Agents | Original Policy Date: | March 13, 2015 |
| Subject: | Rayos | Page: | 1 of 5 |

Last Review Date: June 16, 2022

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).

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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

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- 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

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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 |

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|---------------|---|
| 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 |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.