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METHOTREXATE INJECTIONS

Otrexup, Rasuvo, RediTrex (methotrexate)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Otrexup, Rasuvo, and RediTrex are types of medication that mimics folate, a natural human vitamin, to interfere with the growth of quickly dividing cells in the body. By lowering the ability of these cells to replicate, the immune system is unable to respond as quickly or effectively. This process decreases symptoms of diseases where the immune system of a person attacks itself (autoimmune), such as rheumatoid arthritis and psoriasis. Otrexup and Rasuvo are injected underneath the skin via an auto-injector device. RediTrex is available as a single-dose pre-filled syringe. Other forms of methotrexate include oral tablets and solutions for injection. Otrexup, Rasuvo, and RediTrex are only for once a week use and is not to be used daily (1-3).

Regulatory Status

FDA-approved indications: Otrexup, Rasuvo, and RediTrex are folate analog metabolic inhibitors indicated for: (1-3)

Rheumatoid Arthritis (RA) including Polyarticular Juvenile Idiopathic Arthritis (pJIA) – Otrexup, Rasuvo, and RediTrex are indicated in the management of patients with severe, active rheumatoid arthritis (RA) or children with active polyarticular juvenile idiopathic arthritis (pJIA), who are not intolerant of or had an inadequate response to first-line therapy.

Psoriasis – Otrexup, Rasuvo, and RediTrex are indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy.

Limitations of Use – Otrexup, Rasuvo, and RediTrex are not indicated for the treatment of neoplastic diseases (1-3).

Otrexup, Rasuvo, and RediTrex carry boxed warnings regarding severe toxic reactions, including embryo-fetal toxicity. Otrexup, Rasuvo, and RediTrex should only be prescribed by physicians with experience with antimetabolites therapy. Because of the potential for possibly fatal and toxic reactions, Otrexup, Rasuvo, and RediTrex should only be used in patients with severe and disabling RA or psoriasis that is not responsive to other therapies. Close monitoring for acute



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and/or chronic bone marrow, liver, lung, skin, and kidney toxicities is required (1-3).

Because methotrexate has been reported to cause fetal death and/or congenital anomalies, Otrexup, Rasuvo, and RediTrex are contraindicated in pregnant women. Use in women of reproductive potential without a reliable form of birth control is not recommended (1-3).

Prolonged use of methotrexate can cause hepatic fibrosis and cirrhosis. Liver enzyme elevations are commonly seen but are not always indicative of hepatic disease; therefore, periodic liver biopsies are recommended for those under long term methotrexate treatment (1-3).

Summary

Otrexup, Rasuvo, and RediTrex are folate analog metabolic inhibitors indicated for the treatment of Polyarticular Juvenile Idiopathic Arthritis (pJIA), moderately to severely Active Rheumatoid arthritis (RA), and active psoriasis (PsO), who have failed other first-line therapies. Otrexup, Rasuvo, and RediTrex carry boxed warnings regarding severe toxic reactions, including embryo-fetal toxicity. Close monitoring for acute and/or chronic bone marrow, liver, lung, skin, and kidney toxicities is required (1-3).

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

References

1. Otrexup [package insert]. Ewing, NJ: Antares Pharma, Inc; December 2019.
2. Rasuvo [package insert]. Chicago, IL: Medexus Pharma, Inc; March 2020.
3. RediTrex [package insert]. Nashville, TN: Cumberland Pharmaceuticals Inc.; March 2023.