RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Otrexup and Rasuvo 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. Other forms of methotrexate include oral tablets and solutions for injection. Otrexup and Rasuvo are only for once a week use and is not to be used daily (1,2).

Regulatory Status
FDA-approved indication: Otrexup and Rasuvo are folate analog metabolic inhibitors indicated for (1,2):

**Rheumatoid Arthritis (RA) including Polyarticular Juvenile Idiopathic Arthritis (pJIA)** - Otrexup and Rasuvo 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 and Rasuvo 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 and Rasuvo are not indicated for the treatment of neoplastic diseases (1,2).

Otrexup and Rasuvo carry boxed warnings regarding severe toxic reactions, including embryo-fetal toxicity. Otrexup and Rasuvo should only be prescribed by physicians with experience with antimetabolites therapy. Because of the potential for possibly fatal and toxic reactions, Otrexup and Rasuvo should only be used in patients with severe and disabling RA or psoriasis that is not responsive to other therapies. Close monitoring for acute and/or chronic bone marrow, liver, lung, skin, and kidney toxicities is required (1,2).

Because methotrexate has been reported to cause fetal death and/or congenital anomalies,
Otrexup and Rasuvo are contraindicated in pregnant women. Use in women of child bearing age without a reliable form of birth control is not recommended (1,2).

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 (1,2).

Summary
Otrexup and Rasuvo 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, who have failed other first-line therapies. Otrexup and Rasuvo 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 (1-2).

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

References