PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Xeljanz/Xeljanz XR (tofacitinib)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel & Humira QUANTITY LIMIT— 5 mg tablet—60 per 30 days 11 mg XR tablet—30 per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Xeljanz/Xeljanz XR (tofacitinib) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
5. Member must have tried and failed treatment with **both** Enbrel and Humira.
6. **Dosage allowed:** Xeljanz is 5 mg twice daily; Xeljanz XR is 11 mg once daily.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Xeljanz/Xeljanz XR (tofacitinib) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Alopecia

- Dry eye disease
- Inflammatory bowel diseases (Crohn's disease and ulcerative colitis)
- Prevention of organ transplant rejection
- Psoriasis
- Psoriatic arthritis

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Xeljanz/Xeljanz XR created. Policy SRx-0042 archived. For diagnosis of RA: trial of Humira required. List of diagnoses considered not medically necessary was added.

References:

1. Xeljanz [package insert]. New York, NY: Pfizer; February, 2016.
2. American College of Rheumatology. Guidelines for the management of rheumatoid arthritis: American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Arthritis Rheuma. 1996;39(5):713-723.
3. Fleischmann R, Kremer J, Cush J, et al. Placebo-controlled trial of tofacitinib monotherapy in rheumatoid arthritis. N Engl J Med. 2012b;367(6):495-507.
4. Singh JA, Furst DE, Beharat A, et al. 2012 Update the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2012;64(5):625-639.

Effective date: 07/01/2017
Revised date: 05/10/2017