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Policy Number: C10411-A

Enbrel (etanercept)

PRODUCTS AFFECTED

Enbrel (etanercept)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderately to severely active rheumatoid arthritis, Juvenile idiopathic arthritis, Active psoriatic arthritis, Active ankylosing spondylitis, Moderate to severe chronic plaque psoriasis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:
1. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label

AND

2. Member is not on concurrent treatment or will not be used in combination with other TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Enbrel (etanercept) include: patients with sepsis]

B. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:
1. Documentation of moderate to severe rheumatoid arthritis diagnosis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
OR
(b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND member has tried one additional disease-modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months
(NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the member has already had a 3-month trial of at least one biologic. These members who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD)

C. JUVENILE IDIOPATHIC ARTHRITIS:
1. Documented diagnosis of juvenile idiopathic arthritis in a pediatric member
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) FOR ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS:
    i. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (12 weeks) of one NSAID or glucocorticoid
    AND
    ii. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (12 weeks) of one of the following: methotrexate, leflunomide, anakinra (Kineret), canakinumab (Ilaris), or tocilizumab

OR

(b) FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of one or more of the following: Methotrexate, hydroxychloroquine, sulfasalazine, leflunomide

D. PSORIATIC ARTHRITIS (PsA):
1. Documentation of active psoriatic arthritis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Documented treatment failure, serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
OR
(b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of

inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]
OR
(c) Documentation member has severe psoriasis [PASI ≥12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]

E. CHRONIC PLAQUE PSORIASIS:
1. Documented diagnosis of moderate to severe psoriasis (BSA ≥ 3%) OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g. face, neck, hands, feet, genitals)
AND
2. (a) Documentation of treatment failure or serious side effects to TWO of the following systemic therapies for ≥3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
OR
(b) Documentation of treatment failure to Phototherapy for ≥3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation. Provider to submit documentation of duration of treatment, dates of treatment, or number of sessions.
OR
(c) Documentation of contraindication to systemic therapy and phototherapy
NOTE: Contraindications to phototherapy include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time.
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

F. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:
1. Documented diagnosis of ankylosing spondylitis
AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
AND
3. FOR MEMBER WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to a trial (≥3 consecutive months) of methotrexate OR sulfasalazine
AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]

AND

4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
MODERATE TO SEVERE RHEUMATOID ARTHRITIS, JUVENILE IDIOPATHIC ARTHRITIS, MODERATE TO SEVERE ANKYLOSING SPONDYLITIS: Prescribed by or in consultation with a board-certified rheumatologist
PSORIATIC ARTHRITIS (PsA): Prescribed by or in consultation with a board-certified rheumatologist or dermatologist
CHRONIC PLAQUE PSORIASIS: Prescribed by or in consultation with a board-certified dermatologist
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
CHRONIC PLAQUE PSORIASIS: 4 years of age and older
JUVENILE IDIOPATHIC ARTHRITIS, PSORIATIC ARTHRITIS: 2 years of age and older
ALL OTHER INDICATIONS: 18 years of age and older

QUANTITY:
Adult RA and PsA: 50 mg once weekly
AS: 50 mg once weekly
Adult PsO: 50 mg twice weekly for 3 months followed by 50 mg once weekly
Pediatric PsO or JIA or juvenile psoriatic arthritis: 0.8 mg/kg weekly, maximum 50 mg per week

When requests for off-label dosing, dose escalation, or dose intensification are received, requests will be reviewed for evidence that current or standard dosing is not adequate to produce a therapeutic level of drug (e.g., pharmacokinetic failure), clinical failure or significant loss of response is present, and the requested dosing is established as safe and effective for the condition. There are certain situations where no additional amount of drug is likely to produce or recapture clinical effect because the condition is no longer responsive to the drug (e.g., pharmacodynamic failure) or the drug cannot reach the site of activity at sufficient levels. Review the following items to determine if the requested dosing is medically necessary:

1. *FDA or compendium-supported dosing and therapeutic monitoring recommendations for the drug*
   AND
2. *Member claims/adherence history*
   AND
3. *Clinical documentation of the member's response to current or standard dosing regimens (disease activity indices if commonly used in clinical practice or documentation to approximate them may be necessary to demonstrate the response)*
   AND
4. *In conjunction with documented clinical failure or loss of response or wearing off of effect, test results that demonstrate failure of current or standard dosing to reach established treatment thresholds (e.g., established therapeutic monitoring recommendations)*
   AND
5. *If applicable, documentation showing the member does not have conditions which make achieving a therapeutic level of drug unlikely even with dose intensification (e.g., dose intensification may be futile due to the presence of anti-drug antibodies, protein losing enteropathy, nephrotic syndrome, severe drug excretion or malabsorption issues, etc.)*
   AND
6. *In certain situations, documentation or peer-to-peer determination that re-induction cannot be tried to recapture response as an alternative to long term dose escalation or intensification*

Maximum Quantity Limits –
Enbrel Sure Click Auto-Injector 50 mg/mL- 4 auto-injectors per 28 days
Enbrel Injection kit 25 mg - 8 vials per 28 days
Prefilled syringe 25 mg/0.5 mL - 8 syringes per 28 days
Prefilled syringe 50 mg/mL - 4 syringes per 28 days
Starting dose for plaque psoriasis only: For patients with psoriasis who may require higher doses for the first 12 weeks of therapy, eight 50 mg injections every 28 days may be approved for 12 weeks

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Soluble Tumor Necrosis Factor Receptor Agents

FDA-APPROVED USES:
Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). Enbrel can be initiated in combination with methotrexate (MTX) or used alone.

Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older

Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in adult patients with psoriatic arthritis (PsA). Enbrel can be used with or without methotrexate.

Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS).

Indicated for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

Indicated for the treatment of active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older.

COMPENDIAL APPROVED OFF-LABELED USES:
Systemic juvenile idiopathic arthritis

APPENDIX

APPENDIX:
Appendix A:
OBJECTIVE MEASURES FOR RA:
[Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Member Activity Scale (PAS or PAS-II), Routine Assessment of Member Index Data with 3 measures, Simplified Disease Activity Index (SDAI)]

OBJECTIVE MEASURES FOR PJIA:
Global Arthritis Score (GAS), Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS), Disease

Activity Score based on 28-joint evaluation (DAS28), Simple Disease Activity Index (SDAI), Health Assessment Questionnaire disability index (HAQ-DI), Visual Analogue Scale (VAS), Likert scales of global response or pain by the member or global response by the physician, Joint tenderness and/or swelling counts, Laboratory data

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Etanercept (Enbrel) is a dimeric soluble form of the extracellular ligand-binding human 75 kilodalton(p75) tumor necrosis factor (TNF) receptor that is fused to the Fc fragment of human immunoglobulin (IgG1). Tumor necrosis factor-alpha is a naturally occurring cytokine playing a central role in the immunoregulatory process. Etanercept inhibits binding of tumor necrosis factor- alpha and tumor necrosis factor-beta to cell surface tumor necrosis factor receptors, thereby reducing the inflammatory response. Enbrel is indicated for the following uses: 1. reducing the signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderate or severe active rheumatoid arthritis (RA)1-6; AND 2. reducing the signs and symptoms of moderate or severe active polyarticular juvenile idiopathic arthritis (JIA) in patients aged ≥ 2 years1,7; AND 3.reducing the signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA)1,8; AND 4. for reducing signs and symptoms in patients with active ankylosing spondylitis (AS)1,9; AND 5. for treatment systemic therapy or phototherapy.1,10-11 For RA and PsA, Enbrel can be used in combination with methotrexate (MTX) or used alone.

Crohn's Disease: In a double-blind, placebo-controlled trial Enbrel was not effective for the treatment of moderate to severe Crohn's disease. However, arthritis (spondyloarthropathy, ankylosing spondylitis) may be associated with Crohn's disease and Enbrel may be effective for the spondyloarthropathy in these patients.

Inflammatory Myopathies (Polymyositis, Dermatomyositis, Inclusion Body Myositis): Information is conflicting. In one retrospective review of eight patients with either dermatomyositis or polymyositis some patients responded (improved motor strength and decreased fatigue) to treatment with Enbrel. In this case series, Enbrel was added on to treatment with corticosteroids, intravenous immunoglobulin (IVIG), and DMARDs; there were no standardized outcome measures. In another case series in patients (n = 5) with dermatomyositis who had not responded to steroids and cytotoxic therapy (MTX, azathioprine, cyclosporine), the cytotoxic drugs were discontinued, and Enbrel was given for at least 3 months. All patients had exacerbation of disease and Enbrel was stopped. In a 1-year, double-blind study, patients were randomized to receive Enbrel 50 mg weekly (n = 11) or placebo (n = 5). All patients who received placebo were judged as treatment failures whereas five patients in the Enbrel group were successfully weaned off of prednisone. More studies are needed demonstrating the efficacy of Enbrel and its long-term effects. In a 6-month open-label study of Enbrel in patients with refractory juvenile dermatomyositis (n = 9), minimal improvement was noted in disease activity with some patients experiencing worsening disease.

Hidradenitis Suppurativa: A prospective, randomized, double-blind, placebo-controlled study assigned patients (n = 20) to treatment with Enbrel 50 mg twice weekly or placebo for 12 weeks. Following 12 weeks of treatment, all patients received open-label Enbrel for an additional 12 weeks. The study found no statistically significant difference between Enbrel 50 mg twice weekly and placebo among physician global assessment, member global assessment, and the Dermatology Life Quality Index (DLQI) at Week 12 or Week 24. A systematic review (2013) extracted data from case reports and RCTs and recommended against the use of Enbrel for treatment of hidradenitis suppurativa.

Polymyalgia Rheumatica (PMR): ACR/EULAR guidelines for the management of PMR (2015) strongly recommend against the use of TNF is for treatment of PMR.58 This recommendation is based on lack of evidence for benefit as well as considerable potential for potential harm. While Enbrel has been evaluated in small numbers of patients with PMR, efficacy has not been established.

Sarcoidosis, Ocular: Recommendations for the use of TNF is in ocular inflammatory disorders from the AAO (2014) note that Remicade or Humira may be considered as second-line immunomodulary therapy for patients failing or intolerant of standard immunomodulatory agents.21 A discretionary recommendation (indicating trade-offs are less certain) is that Enbrel should not be used in the treatment of ocular sarcoidosis (moderate-quality evidence). In a double-blind study, patients (n = 18) with chronic ocular sarcoidosis and ongoing inflammation were randomized to Enbrel or placebo for 6 months. Patients had received ≥ 6 months of therapy with MTX and were currently on corticosteroids. For most of the patients, therapy with Enbrel was not associated with significant improvement.

Sarcoidosis, Pulmonary: In a prospective, open-label trial in patients with Stage II or III progressive pulmonary sarcoidosis, treatment with Enbrel was frequently associated with early or late treatment failure.63 This trial was ended early because an excessive number of patients (n = 11/17) had disease progression on Enbrel. Recommendations for best practice in the management of pulmonary and systemic sarcoidosis mention Humira and Remicade as therapeutic options for management of disease

Large Vessel Vasculitis (e.g., Giant Cell Arteritis, Takayasu's Arteritis): Guidelines from EULAR for the management of large vessel vasculitis (e.g., giant cell arteritis, Takayasu's arteritis) do not mention the use of TNFis.65 Additionally, a meta-analysis of RCTs did not find evidence supporting remission or reduction of corticosteroid dose with the use of TNFs in large vessel vasculitis. In a double-blind trial patients with biopsy proven giant cell arteritis with AEs due to corticosteroids were randomized to Enbrel25 mg twice weekly (n = 8) or placebo (n = 9) for 12 months. Corticosteroids were continued but were reduced if possible, according to a predefined protocol. The primary outcome was the ability to withdraw the corticosteroid therapy and control disease activity at 12 months. After 12 months, 50% of Enbrel patients and 22.2% of placebo patients were able to control the disease without corticosteroid therapy (not statistically significant). But patients on Enbrel had a significantly lower dose of accumulated prednisone during the first year of treatment (P = 0.03). In a retrospective single center study in patients with refractory Takayasu's arteritis (n = 25), patients were treated with Remicade (n = 21) or Enbrel (n = 9).68 Five patients who were initially treated with Enbrel were switched to Remicade. Therapy with anti-TNF agents was associated with remission in many patients and dose reduction or discontinuation of prednisone and other immunosuppressant therapies. A randomized controlled trial is needed to better define the efficacy and safety of Enbrel.

Wegener's Granulomatosis: Enbrel is not effective in the induction or maintenance of disease remissions in patients with Wegener's. In a double-blind trial, 180 patients with active Wegener's granulomatosis were randomized to Enbrel or placebo in combination with standard therapies (e.g., cyclophosphamide, MTX, corticosteroids) depending on disease severity.69 When remission was achieved, standard medications were tapered according to protocol guidelines. Patients were enrolled over 28 months and the mean follow- up was 27 months. Of the 174 patients who were evaluable, 126patients (72.4%) achieved sustained remissions, but only 86 patients overall (49.4%) maintained their disease remissions throughout the trial.

There were no differences between Enbrel and the control group in the percent of patients achieving sustained remissions (69.7% vs. 75.3%, P = 0.39); in the percent of patients with sustained periods of low disease activity (86.5% vs. 90.6%); or time to achieve these outcomes. Disease flares were common in both groups. AEs were frequent and often severe. During the study, 56.2% of patients on Enbrel and 57.1% on placebo had at least one severe or life-threatening AE or died. Six of the Enbrel patients and none of the controls developed solid malignancies. Use of Enbrel in patients with Wegener's granulomatosis who are receiving immunosuppressant drugs is not recommended.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Enbrel (etanercept) are considered experimental/investigational and therefore, will follow

Molina's Off-Label policy. Contraindications to Enbrel (etanercept) include: Enbrel should not be administered to patients with sepsis, do not start Enbrel during an active infection, avoid concurrent administration with live vaccines.

Concurrent Use with a Biologic DMARD or Targeted Synthetic DMARD: Enbrel should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition. Combination therapy is generally not recommended due to a higher rate of AEs with combinations and lack of data supportive of additional efficacy. Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Enbrel.

OTHER SPECIAL CONSIDERATIONS:

Enbrel has a black box warning for serious infections and malignancies. Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens. Enbrel should be discontinued if a patient develops a serious infection or sepsis during treatment. Perform test for latent TB; if positive, start treatment for TB prior to starting Enbrel. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF-blockers, including Enbrel.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
N/A	N/A

AVAILABLE DOSAGE FORMS:

Enbrel SOLR 25MG
Enbrel Mini SOCT 50MG/ML single-dose prefilled cartridge
Enbrel SureClick SOAJ 50MG/ML single-dose prefilled autoinjector
Enbrel SOSY 25MG/0.5ML single-dose prefilled syringe
Enbrel SOSY 50MG/ML single-dose prefilled syringe
Enbrel SOLN 25MG/0.5ML single-dose vial

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SUMMARY OF REVIEW/REVISIONS	DATE
Required Medical Information References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q4 2024
REVISION- Notable revisions: Age Restrictions Quantity FDA-Approved Uses References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q4 2023
Q2 2022 Established tracking in new format	Historical changes on file