MRN:_____

DOB:_____

STANDARD Lemtrada® (alemtuzumab) PLAN OF TREATMENT

NOTE: Patient ***may be ineligible*** to receive alemtuzumab if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, severe abdominal pain or vomiting, and/or surgery.

1. Patient Name:_____ Height (inches):_____ Weight (lbs):_____

2. Allergies: _____

3. Diagnosis: □ **G35 Relapsing Multiple Sclerosis**

4. Pre-medications: Administered at minimum of 30-60 minutes prior to infusion **as selected:**

**** Premedication of Acetaminophen PO, Diphenhydramine IVP, and Ondansetron IVP is suggested prior to infusion***

Acetaminophen:	**Diphenhydramine:** □ 25 mg IVP, □ 50mg IVP, □ 25 mg PO, □ 50mg PO or
□ 1000 mg PO □ 650 mg PO □ 500 mg PO □ 325 mg PO	Alternate oral antihistamine to diphenhydramine: □ Cetirizine 10 mg □ Loratadine 10 mg Fexofenadine □ 60mg or □ 180mg Famotidine: □ 20mgs PO, □ 40mgs PO, □ 20mgs IVP, □ 40mgs IVP **Ondansetron:** □ 4 mg IVP, □ 4 mg PO, □ other:_____

Pre-medicate with other: _____

5. Orders:

Methylprednisolone 1000 mg IV over 1 hour in Sodium Chloride 0.9% diluted per protocol for the **first 3 days of each treatment course** prior to Lemtrada®

Lemtrada® (alemtuzumab) 12 mg IV in 100 ml of Sodium Chloride 0.9% to infuse over 4 hours, followed by **(2) two hour post infusion monitoring after each dose**.

6. Frequency:

□ First treatment course: daily x 5 consecutive days or

□ Second treatment course: daily x 3 consecutive days

Special orders: _____

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES

7. Physician's Signature:_____/_____ Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials:_____ NPI: _____

MRN:_____

DOB:_____

Guidelines for Prescribing Lemtrada® (alemtuzumab)

(Required documentation with all initial referrals)

Patient Name: _____ **Referral Date:**_____

☐ Because of the risk of autoimmunity, infusion reactions, and malignancies, LEMTRADA is available only through restricted distribution under a Risk Evaluation Mitigation Strategy (REMS) Program. Call 1-855-676-6326 to enroll in the LEMTRADA® REMS program.

☐ Include signed and completed **Plan of Treatment**.

☐ Include patient demographic information and insurance information. (Copy of insurance cards if available)

☐ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis.**

• LEMTRADA® is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

☐ If patient is switching biological therapies, then MD must specify wash-out period prior to starting Lemtrada® as specified of_____weeks. Last known biological therapy:_____and last date received:_____.

Pre-Screening: (* TB screening results must be available prior to start of therapy and within last 12 months. If screening results are positive or indeterminate, then a negative CXR result is required.)

☐ **Has antiviral prophylaxis for herpetic viral infections been prescribed?** □ Yes □ No

☐ **Are immunizations current and if any recently given, were they at least 6 weeks prior to start of Lemtrada?** □ Yes □ No

☐ **Required TB screening results: PPD or QuantiFERON Gold Test.***

☐ **CBC with differential, serum creatinine level, urinalysis with urine cell counts, & TSH levels prior to start of therapy.**

** Warnings/Precautions: • LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia (ITP) and anti-glomerular basement membrane disease. • **Clinical Lab Monitoring: Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts and thyroid stimulating hormone (TSH) prior to start of therapy and at periodic intervals for 48 months after the last dose**. • **Life threatening infusion reactions:** Monitor patients for two hours after each infusion. Make patients aware that serious infusion reactions can also occur after the 2-hour monitoring period. •LEMTRADA may cause an increased risk of malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams. • **Adverse Reactions:** Most common (incidence ≥10% and > interferon beta-1a): rash, headache, pyrexia, nasopharyngitis, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infection, urticaria, pruritus, thyroid gland disorders, fungal infection, arthralgia, pain in extremity, back pain, diarrhea, sinusitis, oropharyngeal pain, paresthesia, dizziness, abdominal pain, flushing, and vomiting. • **Contraindicated** in patients who are infected with Human Immunodeficiency Virus (HIV) because LEMTRADA causes prolonged reductions of CD4+ lymphocyte counts. •***Pregnancy Category C***. See full prescribing information.

Checklist for referrals to AccuRX Infusion Center:

Fax referral to 1-866-990-3192

- Patient demographics – address, phone number, SS#, etc.
- Insurance Information – copy of the card(s) if possible
- Plan of Treatment/Orders
- Most recent physician office notes to include tried and failed therapies – all insurance companies that require a pre-authorization require the note. This includes Medicare/Medicaid HMOs
- Any lab results or other diagnostic procedures to support the diagnosis

AccuRx Infusion Center will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.