

## Mandell Center Medication Protocol: Kesimpta (ofatumumab)

### Indications and Usage:

- For relapsing forms of Multiple Sclerosis (MS): Clinically Isolated Syndrome, Relapsing-Remitting MS and active Secondary Progressive MS.

### Prior to initiating Kesimpta, the following are required:

#### *Labwork:*

- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody IgM
- Serum immunoglobulins (IgM, IgG, IgA)
- CBC with differential within 1 month if change in therapy, or 2 months if new DMT

#### *Imaging:*

- MRI Brain (with or without contrast per provider) to be performed in the 3 months prior or within 2 months of starting Kesimpta for relapsing-remitting patients (may also be performed at provider discretion).

\*For patients transitioning from Tysabri, MRI brain with and without contrast to be performed for JCV positive patients upon discontinuing Tysabri and at 6 months after discontinuing Tysabri.

- MRI Brain (with or without contrast) to be performed at provider discretion for patients with progressive forms of MS.

### Vaccinations:

- Administer according to immunization guidelines at least 4 weeks prior to initiation of Kesimpta for live or live-attenuated.
- Administer inactivated vaccines 2 weeks prior to initiation of Kesimpta.

### Contraception:

- Advise females of reproductive potential to use effective contraception while receiving Kesimpta and for at least 6 months after the last dose.

### Dosing:

- Initial dose of 20 mg/0.4mL SQ at Weeks 0, 1, and 2 followed by
- Subsequent dosing of 20 mg/0.4mL SQ once monthly starting at Week 4



**Administration:**

- Before administration, remove Kesimpta sensoready pen from refrigerator and allow to reach room temperature for 15-30 minutes.
- Administer in abdomen, thigh, or outer upper arm subcutaneously.
- First injection of Kesimpta should be performed after nursing training and/or under the guidance of a healthcare professional.

**Delayed or Missed Doses:**

- If you miss an injection of Kesimpta at Week 0, 1, or 2, administer it as soon as possible without waiting until the next scheduled dose. After that, give your Kesimpta injections one month apart.

**Management of Medication Reaction:**

- Injection related reactions may occur within 24 hours and predominantly following the first injection. Notify your provider if you experience the following:
  - Local: erythema, swelling, itching, and pain
  - Systemic: Predominantly mild to moderate -fever, headache, myalgia, chills and fatigue (no life-threatening reactions in the RMS clinical studies) highest with first injection (14.4%, then 4.4% with second, < 3% with third)

**Patient Counseling:**

- Advise patients to contact provider for any signs of infection during treatment or after the last dose. Signs include but are not limited to: fever, chills, constant cough, or dysuria.
- Advise that Kesimpta may cause reactivation of hepatitis B infection and monitoring will be required if they are at risk.

**Follow-up and Monitoring:**

- Perform Serum Immunoglobulins q 6 months, with opportunistic or recurrent infections, and after discontinuation of therapy until B- Cell repletion.
- CBC with differential every 6 months.
- Annual MRI Brain and C-Spine without contrast (or per provider discretion).
- Initial follow up with provider in 3 months, then every 6 months.

Dr. Mary A. Bailey, Regional Director

Date

Mandell Multiple Sclerosis Center

Reference: Kesimpta PI revision 8/2020