Ofatumumab (KESIMPTA and ARZERRA)
Criteria for Use
May 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive ofatumumab.

- ☐ Diagnosis of primary progressive multiple sclerosis (PPMS) or secondary progressive multiple sclerosis without activity (i.e., non-active SPMS)
- ☐ History of life-threatening infusion reaction to another anti-CD20 antibody (e.g., ublituximab, rituximab)
- ☐ Untreated active hepatitis B infection
- ☐ Untreated latent or active tuberculosis infection
- ☐ Concurrent use of another disease modifying therapy (DMT) to treat multiple sclerosis (MS) unless the previous agent will be discontinued when ofatumumab is initiated
- ☐ Active infection or receiving chemotherapy
- ☐ Pregnancy

Inclusion Criteria

All of the following criteria must be met.

- ☐ Care is provided by a VA/VA Community Care neurologist or locally designated MS expert (e.g., Spinal Cord Injury)
- ☐ Diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting MS, active secondary progressive MS, or clinically isolated syndrome) has been established
- ☐ Intolerance or inadequate therapeutic response to ublituximab OR patient not a candidate for IV anti-CD20 antibody therapy due to inability to access an infusion center or poor venous access
- ☐ Patient has been screened for hepatitis B virus (HBV) including HBsAg, HBsAb and HBcAb. If HBsAb negative and HBcAb positive or HBsAg positive, a liver disease expert must be consulted first. ^1
- ☐ Quantitative serum immunoglobulins tested. If low, neurologist has documented risk/benefit assessment and/or an immunology expert was consulted prior to start
- ☐ All guideline recommended eligible immunizations administered at least 4 weeks prior to the start of treatment for live or live-attenuated vaccines, and whenever possible, at least 2 weeks prior to the start of treatment for inactivated vaccines

Additional Inclusion Criteria

One of the following criteria must be met.

☐ Current treatment with natalizumab and patient has elevated risk factors for PML (anti-JC virus antibody positive, duration of therapy > 24 months or received immunosuppressant therapy prior to natalizumab) ^2

☐ Ineffectiveness with at least one other MS DMT defined as: continued clinical relapses, central nervous system (CNS) lesion progression on MRI, or continued worsening of disability ^3

☐ Highly active disease demonstrated by heavy burden of gadolinium enhancing and/or T2 lesions on MRI at onset of disease, high accumulation of CNS lesions on MRI, or rapid accrual of disability ^3

Additional Inclusion Criteria

Select if applicable:

☐ For patients who can become pregnant: Pregnancy should excluded prior to receiving ofatumumab

☐ For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 6 months after stopping treatment

Other Justification

Select the following for ARZERRA (oncologic indications, not multiple sclerosis):

☐ _____

Footnotes

1. HBsAg: Hepatitis B surface antigen; HBsAb: Hepatitis B surface antibody; HBcAb: Hepatitis B core antibody
2. PML (progressive multifocal leukoencephalopathy) is a severe demyelinating disease of the central nervous system caused by reactivation of the JC (John Cunningham) polyomavirus.
3. Measurements of worsening disability can include, but are not limited to, decreased mobility, decreased ability to perform activities of daily living due to disease progression, or an increase in Expanded Disability Status Scale (EDSS) score.

Prepared: 2/2022 Revised: 9/2022, 5/2024. Contact: Natasha Antonovich, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)