Clinical Oversight Review Board (CORB) Criteria for Prescribing/

Obinutuzumab (Gazyva)

Notes:

- Quantity Limits: No (N/A for IV medication)
- ^ Adequate trial is defined as the following:
  - Antimalarial – 60 days
  - Rituximab product – minimum of 3 months has elapsed after receipt of rituximab 1-2 doses
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **obinutuzumab (Gazyva)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **obinutuzumab (Gazyva)** will be covered when the following criteria are met:

1. Prescriber is a nephrologist or a rheumatologist and patient has a diagnosis of active lupus nephritis (LN)
   - Patient is 18 years of age or older
   - Patient has positive antinuclear antibody (ANA), anti-double-stranded deoxyribonucleic acid (anti-dsDNA), and/or Sjogren's antibody (SSA or SSB)
   - Patient is dependent on corticosteroid therapy OR has an intolerance* or contraindication to corticosteroid therapy
   - Patient has failed an adequate trial^, has an intolerance*, or has a contraindication to at least one antimalarial (e.g. hydroxychloroquine, chloroquine)
   - Patient has failed an adequate trial^, has an intolerance*, or has a contraindication to a rituximab product

Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **obinutuzumab (Gazyva)** will be covered on the prescription drug benefit when the following criteria are met:

1. Prescriber is a nephrologist or rheumatologist and patient has a diagnosis of active lupus nephritis (LN)
   - Patient currently stable on obinutuzumab