

Ocrelizumab, Serum Immunoglobulin Levels, and Serious Infections

Overview¹



Impact on IgG and IgM



SI types and outcomes



Ig levels and SI incidence

- After 10 years of continuous treatment, IgG and IgM levels remained normal^a for most patients
- For IgG in particular, levels remained normal^a for >85% of patients over 10 years

- The type, severity, latency, and duration of SIs observed during episodes of IgG<LLN were consistent with the overall SIs observed in patients treated with OCR

- Over a period of up to 10 years, discontinuations due to low IgG, or due to SIs associated with low IgG, were observed in less than 1% of patients (n=20; 0.96%)
- Discontinuations due to SIs during periods of low IgM were observed in less than 1% of patients (n=12; 0.57%)

^aLLN for IgG=5.65 g/L. LLN for IgM=0.4 g/L.

Clinical Trial Population: Change in Serum IgG and IgM Levels over 10 Years¹

Figure 1. Change in serum IgG levels in RMS (A) and PMS (B) populations (quartile trajectories)^a

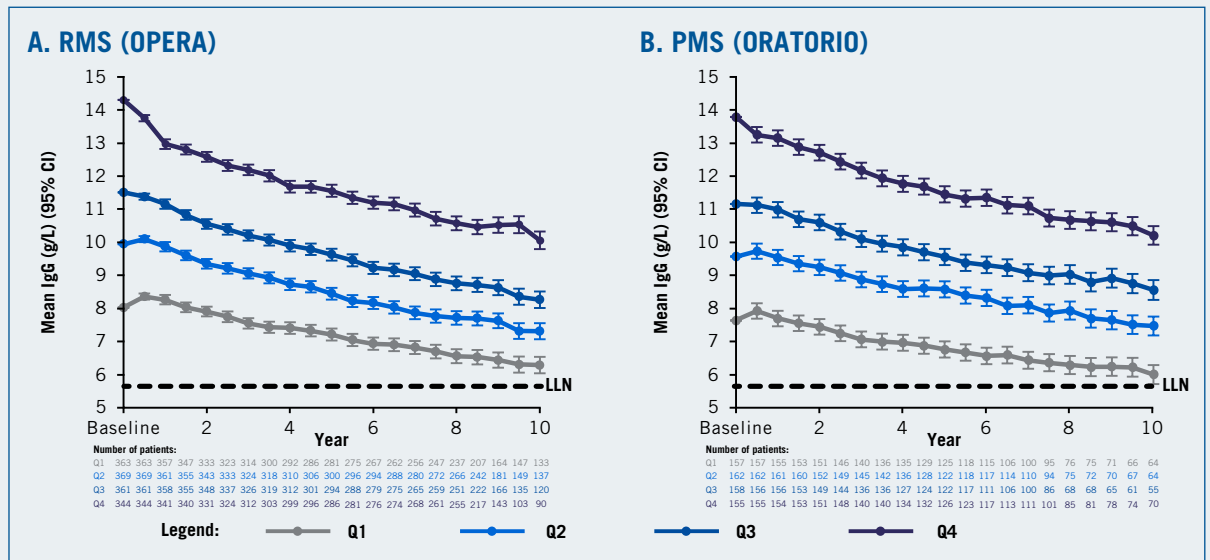
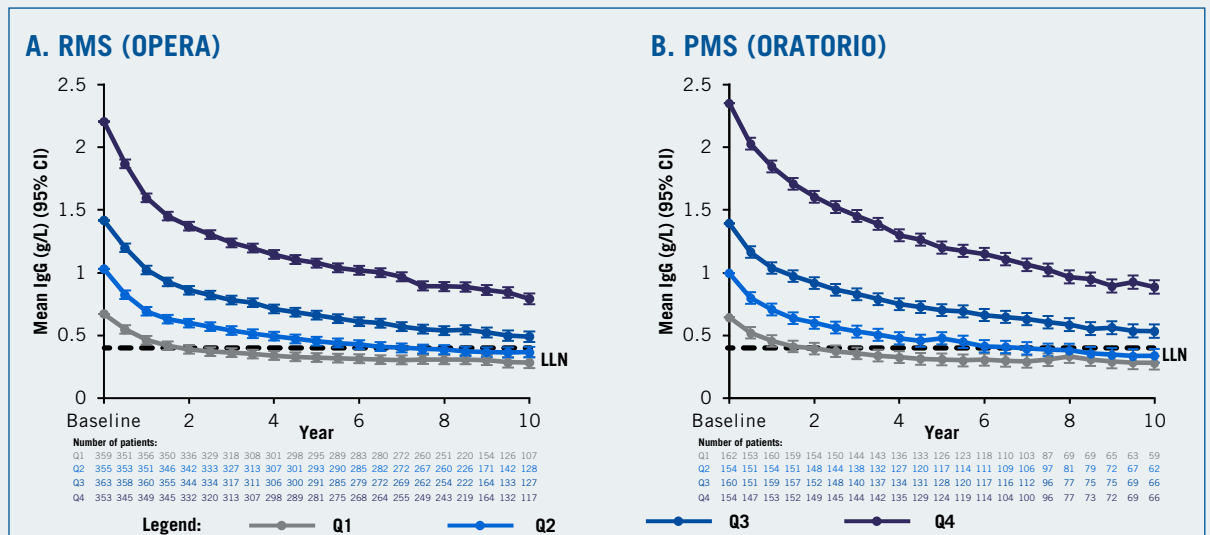


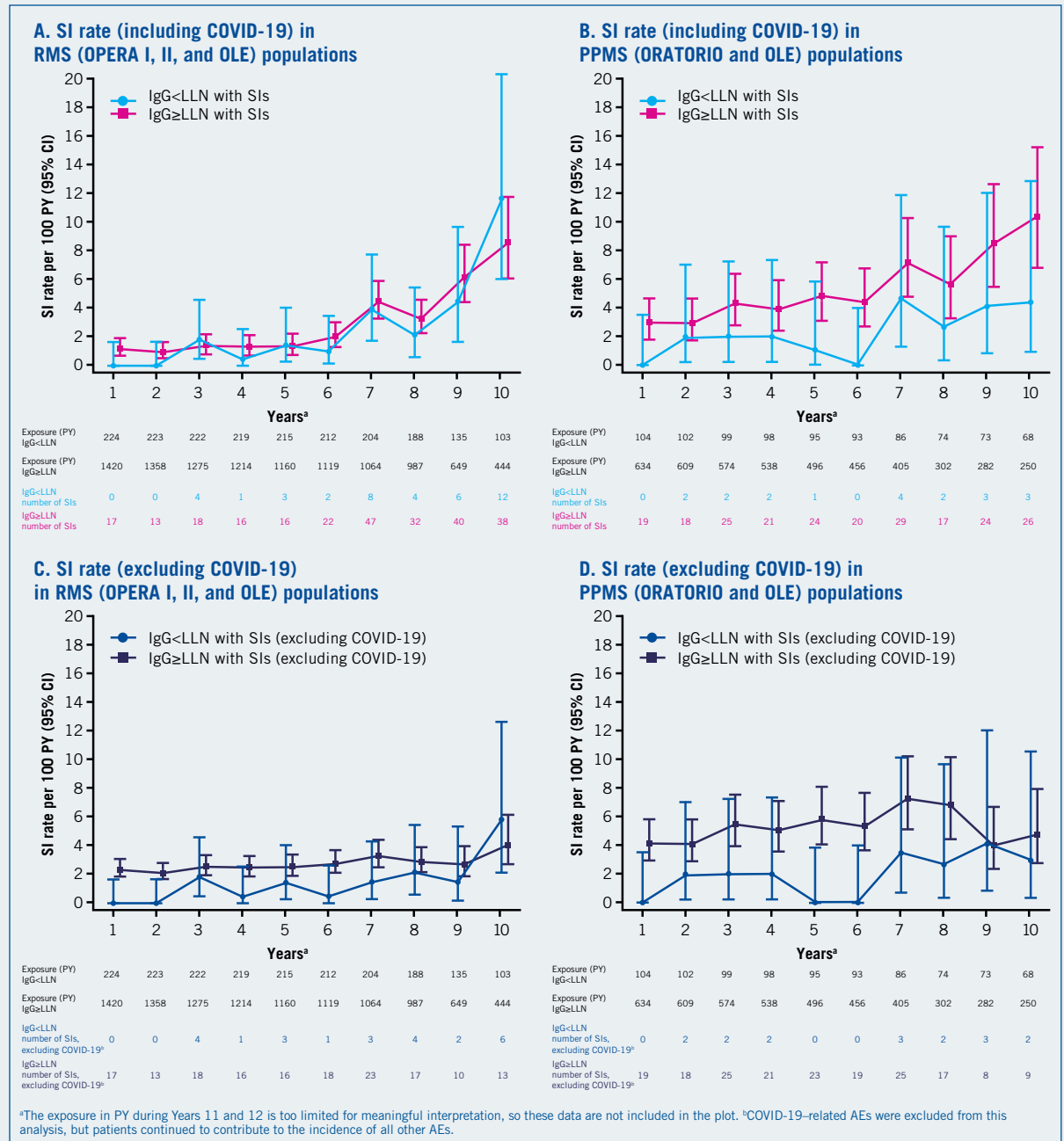
Figure 2. Change in serum IgM levels in RMS (A) and PMS (B) populations (quartile trajectories)^a



^aIncludes patients who received any dose of OCR during the CTP and associated OLE periods of the phase 3 OPERA and ORATORIO studies, including patients originally randomized to comparator (IFN β-1a or placebo) who switched to open-label OCR treatment (data as of November 2022).

Clinical Trial Population: Relationship Between SI Rates and Ig Levels²

Figure 3. SI rate per 100 PY in RMS (A,C) and PPMS (B,D) populations



- The type, severity, latency, and duration of SIs observed during episodes of IgG<LLN were consistent with the overall SIs observed in patients treated with OCR
- The majority of SIs were of Grade 3 intensity, had resolved (regardless of IgG status), and were not treatment limiting

For more information on the rate of infections with OCR treatment, please visit the [Ocrelizumab and infections webpage](#).

The Prescribing Information is the primary source of information on the known and potential risks associated with ocrelizumab.

Abbreviations:

ADL=activities of daily living; AE=adverse event; CTCAE=Common Terminology Criteria for Adverse Events; CTP=controlled treatment period; IFN β-1a=interferon beta-1a; Ig=immunoglobulin; LLN=lower limit of normal; OCR=ocrelizumab; OLE=open-label extension; PMS=progressive multiple sclerosis; PPMS=primary progressive multiple sclerosis; pwMS=patients with multiple sclerosis; PY=patient-years; Q=quarter; RMS=relapsing MS; SI=serious infection.

References:

1. Hauser SL, et al. Presented at:ECTRIMS-ACTRIMS 2023. October 11-13, 2023. Milan, Italy; Poster P304.
2. Genentech. Data on file.

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<https://www.genentech-medinfo.com/our-products/neuroscience/ocrevus.html>

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