Monitor & Optimize

Monitoring provides valuable information that may help you optimize inflammatory bowel disease clinical response to vedolizumab (VDZ)

- Quantifies if patients have sufficient VDZ concentrations and/or have developed antibodies to vedolizumab (ATV), helping you maximize duration of VDZ therapy
- Drug-tolerant assay overcomes limitations of assays that cannot measure both serum drug and antidrug antibody levels in the presence of VDZ
  - No reported interference

Using the RAND/UCLA Appropriateness Method, an expert panel recommended testing for drug and antibody concentrations in the following scenarios:

- After induction in primary nonresponders
- After loss of response (secondary nonresponders)
- When restarting after a drug holiday
- Proactively during maintenance therapy

The incidence and impact of ATV on clinical response is unknown

- Immunogenicity could not be reliably assessed in early VDZ clinical trials due to drug interference with the ELISA assay
- The FDA mandated reanalyzing serum VDZ samples and ATV reporting by March 2017
  - Current ATV rate during treatment phase of UC and CD clinical trials (4%) may be underestimated

NEW
Critical data that may help you:

**Optimize Dosing**

Observed clinical associations between vedolizumab trough level and response during induction from the GEMINI I and II pivotal trials\(^7,8,\ast,\dagger\)

While there is no well-defined VDZ trough level predictive of positive clinical outcomes, observations from several studies include:

- Higher week 6 VDZ levels were associated with mucosal healing at week 6\(^4\)\(\dagger\)
- Week 6 VDZ levels were significantly higher in patients in clinical remission at \(\geq 28\) weeks vs treatment-failure patients \(P < 0.05\)^\(5,\ast,\dagger\)
- Higher VDZ trough levels at week 6 correlated with clinical remission at week 14\(^\ast,\ast\ast\)
- VDZ levels were significantly higher in patients with clinical response at week 14 vs nonresponders \((P = 0.02)\) and higher in steroid-free patients vs steroid-dependent patients\(^12,\dagger\)

\(\ast\)Clinical remission defined as a Mayo score of 2 or lower and no subscore > 1.
- \(\ast\)Clinical remission defined as Crohn’s Disease Activity Index of \(\leq 150\).
- \(\dagger\)Supplemental data from GEMINI II randomized, double-blind, placebo-controlled trials of VDZ induction and maintenance therapy in patients with active UC where serum VDZ levels were reported based off ELISA.\(^7\)
- \(\dagger\)Supplemental data from GEMINI II randomized, double-blind, placebo-controlled trials of VDZ induction and maintenance therapy in CD patients where serum VDZ levels were reported based off ELISA.\(^5\)

**References:**


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