Test Definition: RISA

Risankizumab, Serum

Overview

Useful For

Assessing the response to risankizumab therapy

Assessing the need for dose escalation

Evaluating potential changes or discontinuation of therapy

Monitoring patients who need to be above a certain risankizumab concentration to improve the odds of a clinical response for therapy optimization

Testing Algorithm

For more information see Ulcerative Colitis and Crohn Disease Therapeutic Drug Monitoring Algorithm.

Special Instructions

- Ulcerative Colitis and Crohn Disease Therapeutic Drug Monitoring Algorithm

Method Name

Liquid Chromatography Mass Spectrometry (LC-MS)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

Risankizumab trough levels may be useful to document therapeutic levels and to assess lack of response. For patients not responding properly to therapy, a risankizumab level could aid in the decisions to escalate, de-escalate, or discontinue risankizumab.

Specimen Required

Supplies: Sarstedt Aliquot Tube 5 mL (T914)
Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL

Collection Instructions:
1. Draw blood immediately before the next scheduled dose (trough specimen).
2. Within 2 hours of collection, centrifuge and aliquot serum into plastic vial.

Forms

If not ordering electronically, complete, print, and send Gastroenterology and Hepatology Test Request (T728) with the specimen.

Specimen Minimum Volume

0.25 mL

Reject Due To

Gross hemolysis	OK
Lipemia	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	28 days	
	Ambient	28 days	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Risankizumab (Skyrizi, AbbVie) is a humanized IgG1 kappa therapeutic monoclonal antibody used to treat moderate to severe plaque psoriasis, ulcerative colitis, and Crohn disease. Risankizumab targets interleukin 23A (IL-23p19) binding with high affinity to the p19 subunit and inhibiting further action.

Therapeutic drug monitoring (TDM) has become standard of care in the gastroenterology practice for biologic therapies used in inflammatory bowel disease (IBD), Crohn disease, and ulcerative colitis. TDM is routinely used to assess loss of response to therapy and proactively manage patients taking tissue necrosis factor (TNF) inhibitors (eg, infliximab and adalimumab), alpha-4-beta7 integrins (vedolizumab), or IL12/23 blockers (ustekinumab). With the approval of risankizumab for IBD, TDM is expected to play an important role in managing loss of response to therapy and guide decision making for use of monotherapy or combination therapy.

Risankizumab is currently US Food and Drug Administration-approved for plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn disease.

Patients with plaque psoriasis or psoriatic arthritis are treated with 150 mg subcutaneously at weeks 0, 4, and every 12 weeks thereafter. The steady state maximum concentration (Cmax) and trough concentration (Ctrough) are estimated

to be 12 and 2 mcg/mL, respectively.

Patients with Crohn disease are treated with 600 mg intravenously at weeks 0, 4, and 8, followed by 180 mg or 360 mg subcutaneously at week 12 and every 8 weeks thereafter. During induction weeks 8 through 12, the median Cmax is estimated to be 156 mcg/mL and the Ctrough is estimated to be 38.8 mcg/mL, according to the drug package insert. Steady state is achieved at 28 weeks after starting treatment in the dosing regimen for Crohn disease. Median Cmax and Ctrough concentrations measured during weeks 40 through 48 of maintenance phase (or weeks 52-60 from start of treatment) are estimated to be 14.0 mcg/mL and 4.1 mcg/mL, respectively, for 180 mg dose or 28.0 mcg/mL and 8.1 mcg/mL, respectively, for 360 mg dose.

Risankizumab is immunogenic, like other therapeutic monoclonal antibodies. Clinical trials have shown antibodies-to-risankizumab occur at rates of about 24% for plaque psoriasis, 12% for psoriatic arthritis, and 3.4% for Crohn disease.

Reference Values

Lower limit of quantitation=1.0 mcg/mL

Interpretation

The optimal therapeutic concentration of risankizumab associated with favorable outcomes in inflammatory bowel disease is not known at this time. In Crohn disease, the recommendation is to use the lowest concentration that maintains response. According to the package insert, concentrations of risankizumab at steady state ranged from 4.1 mcg/mL (trough) to 14 mcg/mL (peak) at 180 mg dosing and 8.1 mcg/mL (trough) to 28 mcg/mL (peak) at 360 mg dosing. Steady state is achieved 28 weeks after initiation of therapy for the dosing regimen in Crohn disease.

Other therapeutic thresholds vary according to the disease, treatment regimen, and response or lack of response to therapy.

Cautions

Lipemic samples will be rejected.

Clinical Reference

1. Ladwig PM, Barnidge DR, Willrich MA. Quantification of the IgG2/4 kappa monoclonal therapeutic eculizumab from serum using isotype specific affinity purification and microflow LC-ESI-Q-TOF mass spectrometry. J Am Soc Mass Spectrom. 2017;28(5):811-817
2. Willrich MA, Murray DL, Barnidge DR, et al. Quantitation of infliximab using clonotypic peptides and selective reaction monitoring by LC-MS/MS. Int Immunopharmacol. 2015;28(1):513-520
3. Ladwig PM, Barnidge DR, Willrich MA. Mass spectrometry approaches for identification and quantitation of therapeutic monoclonal antibodies in the clinical laboratory. Clin Vaccine Immunol. 2017;24(5):e00545-16
4. Feagan, B. G., J. Panes, M. Ferrante, et al. Risankizumab in patients with moderate to severe Crohn's disease: an open-label extension study. Lancet Gastroenterol Hepatol. 2018;3(10):671-680
5. Ferrante, M., R. Panaccione, F. Baert, et al. Risankizumab as maintenance therapy for moderately to severely active Crohn's disease: results from the multicentre, randomised, double-blind, placebo-controlled, withdrawal phase 3 FORTIFY maintenance trial. Lancet. 2022;399(10340):2031-2046
6. Skyrizi. Package insert. AbbVie, Inc.; Revised June 2024. Accessed October 4, 2024. Available at www.rxabbvie.com/pdf/skyrizi_pi.pdf

Performance

Method Description
Risankizumab is extracted from serum and measured by liquid chromatography mass spectrometry.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Wednesday

Report Available
2 to 9 days

Specimen Retention Time
2 weeks

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
80299

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
RISA	Risankizumab, S	105041-8

Result ID	Test Result Name	Result LOINC® Value
621304	Risankizumab, S	105041-8