

# Monitor & Optimize

PROMETHEUS®  
**Anser® IFX**

Monitor with PROMETHEUS® Anser® IFX to help optimize infliximab (IFX) therapy during induction, maintenance, and loss of response

## Clinical Associations Between Serum IFX and Antibodies to IFX (ATI) Levels in IBD<sup>1-8</sup>

### END OF INDUCTION



To help achieve long-term response to IFX

**IFX > 5.1 µg/mL:**  
UC clinical response at week 30<sup>1</sup>

**IFX = 4.7 µg/mL:**  
Clinical response in pediatric patients at week 54<sup>2</sup>

**IFX ≥ 3.5 µg/mL:**  
CD clinical response at week 54<sup>3</sup>

### MAINTENANCE



To help use IFX more efficiently/increase likelihood of long-term success

**IFX ≥ 5 µg/mL:**  
Longer duration<sup>4</sup>

**IFX 3-7 µg/mL:**  
More efficient use<sup>5</sup>

### LOSS OF RESPONSE



To identify patients who are ATI+ or have low IFX levels

**ATI > 9.1 U/mL:**  
3.6-fold chance of unsuccessful response to dose escalation<sup>6</sup>

**IFX > 3.8 µg/mL:**  
Lack of response to increased dose<sup>7</sup>

### REMISSION



Associated with<sup>8</sup>:

**ATI < 3.15 U/mL**

**IFX > 3 µg/mL**

# Know their IFX levels. Build your plan.

PROMETHEUS®  
**Anser® IFX**

## LEVELS

## Multiple Studies Associated Serum IFX and/or ATI Levels with Outcomes<sup>1-8</sup>

Induction	
<b>IFX &gt; 5.1 µg/mL</b>	<b>ACT-1 and ACT-2 post hoc analysis of UC patients:</b> IFX > 5.1 µg/mL associated with clinical response in UC patients at week 30 <sup>1,a</sup>
<b>IFX = 4.7 µg/mL</b>	<b>Prospective observational study of 46 pediatric IBD patients:</b> IFX = 4.7 µg/mL (median level) predictive of persistent remission (PR) in pediatric IBD patients at week 54 vs 2.6 µg/mL for patients not in PR ( $P = 0.03$ ) <sup>2,b</sup>
<b>IFX ≥ 3.5 µg/mL</b>	<b>ACCENT-1 post hoc analysis of CD patients (n = 71 in 5 mg/kg group):</b> IFX ≥ 3.5 µg/mL associated with CD clinical response at week 54 without dose escalation <sup>3,a,c</sup>
Maintenance	
<b>IFX ≥ 5 µg/mL</b>	<b>Retrospective, dose-adjustment study of 126 IBD patients:</b> IFX ≥ 5 µg/mL at trough associated with longer duration of IFX therapy without flares ( $P < 0.0001$ ) <sup>4,b</sup>
<b>IFX 3-7 µg/mL</b>	<b>TAXIT randomized, controlled dose-escalation trial of 43 CD and 26 UC patients in stable clinical response:</b> IFX 3-7 µg/mL at trough associated with higher proportion of CD patients in remission ( $P = 0.02$ ) and more efficient use of IFX ( $P < 0.001$ ) <sup>5,a,d</sup>
Loss of response (LOR)	
<b>IFX &gt; 3.8 µg/mL</b>	<b>Retrospective study of 247 IBD patients with 188 IFX LOR events:</b> IFX > 3.8 µg/mL associated with lack of response to IFX dose increase <sup>7,e</sup>
<b>ATI &gt; 9.1 U/mL</b>	<b>Retrospective study where 1,232 serum samples drawn just prior to IFX infusion from 64 CD and 26 UC patients were analyzed:</b> ATI > 9.1 U/mL associated with 3.6-fold likelihood of unsuccessful intervention ( $P = 0.003$ ) <sup>6,f</sup>
Remission	
<b>IFX &gt; 3 µg/mL</b>	<b>Four prospective, randomized clinical trials where 1,487 serum samples from 483 CD patients on maintenance IFX were analyzed:</b> IFX > 3 µg/mL associated with remission (area under the curve [AUC] = 0.681; 95% CI 0.632-0.731) <sup>8,g</sup>
<b>ATI &lt; 3.15 U/mL</b>	<b>Four prospective, randomized clinical trials where 1,487 serum samples from 483 CD patients on maintenance IFX were analyzed:</b> ATI < 3.15 U/mL associated with remission (AUC = 0.632; 95% CI 0.589-0.676) <sup>8,f</sup>

<sup>a</sup>Serum IFX levels were reported based off enzyme linked immunoassay (ELISA).

<sup>b</sup>Serum IFX levels were reported based off PROMETHEUS® Anser® IFX and ELISA.

<sup>c</sup>Patients with and without durable sustained response at week 54 had median 4 and 1.9 µg/mL IFX levels, respectively ( $P = 0.033$ ).

<sup>d</sup>Proportion of CD patients in remission after optimization was 88% vs 65% before dose escalation.

<sup>e</sup>Serum IFX and ATI levels were reported based on ELISA.

<sup>f</sup>Serum ATI levels were reported based off PROMETHEUS Anser IFX.

<sup>g</sup>Serum IFX levels were reported based off PROMETHEUS Anser IFX.

**References:** 1. Adedokun OJ, Sandborn WJ, Feagan BG, et al. Association between serum concentration of infliximab and efficacy in adult patients with ulcerative colitis. *Gastroenterology*. 2014;147(6):1296-1307. 2. Singh N, Rosenthal CJ, Melmed GY, et al. Early infliximab trough levels are associated with persistent remission in pediatric patients with inflammatory bowel disease. *Inflamm Bowel Dis*. 2014;20(10):1708-1713. 3. Cornille F, Hanauer SB, Diamond RH, et al. Postinduction serum infliximab trough level and decrease of C-reactive protein level are associated with durable sustained response to infliximab: a retrospective analysis of the ACCENT 1 trial. *Gut*. 2014;63(11):1721-1727. 4. Vaughn BP, Martinez-Vazquez M, Patwardhan VR, Moss AC, Sandborn WJ, Cheifetz AS. Proactive therapeutic concentration monitoring of infliximab may improve outcomes for patients with inflammatory bowel disease: results from a pilot observational study. *Inflamm Bowel Dis*. 2014;20(11):1996-2003. 5. Vande Casteele N, Ferrante M, Van Assche G, et al. Trough concentrations of infliximab guide dosing for patients with inflammatory bowel disease. *Gastroenterology*. 2015;148(7):1320-1329. 6. Vande Casteele N, Gils A, Singh S, et al. Antibody response to infliximab and its impact on pharmacokinetics can be transient. *Am J Gastroenterol*. 2013;108(6):962-971. 7. Yanai H, Lichtenstein L, Assa A, et al. Levels of drug and antidrug antibodies are associated with outcome of interventions after loss of response to infliximab or adalimumab. *Clin Gastroenterol Hepatol*. 2015;13(3):522-530. 8. Vande Casteele N, Khanna R, Levesque BG, et al. The relationship between infliximab concentrations, antibodies to infliximab and disease activity in Crohn's disease. *Gut*. 2015;64(10):1539-1545.

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