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Coverage Policy/Guideline

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Effective Date: **5/1/2025** Last Review Date: **2/2025;  
4/2025**

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
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	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> Kentucky PRMD

**Dosage and Administration**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**Approval Duration and Quantity Restrictions:**

**Approval:**

Initial and Renewal Approval:

- Immune checkpoint inhibitor-related toxicity without inflammatory arthritis: 6 months
- All other indications: 12 months

**Quantity Level Limit:**

- Remicade (infliximab) injection 100 mg vial: 5 vials per 42 days
- Avsola (infliximab-axxq) injection 100 mg vial: 5 vials per 42 days
- Inflectra (infliximab-dyyb) injection 100 mg vial: 5 vials per 42 days
- Renflexis (infliximab-abda) injection 100 mg vial: 5 vials per 42 days
- Infliximab injection 100 mg vial: 5 vials per 42 days
- Zymfentra (infliximab-dyyb) injection 120 mg prefilled syringe/pen: 2 syringes/pens per 28 days

Exception Limit (based on indication)

Abbreviations: RA = rheumatoid arthritis; PsA = psoriatic arthritis; AS = ankylosing spondylitis; CD = Crohn’s disease; UC = ulcerative colitis; PsO = plaque psoriasis; IV = intravenous; SC = subcutaneous

Dose Type	Indication	Exception Limit
Induction dose	All (excluding high dose pediatric CD and UC, uveitis)	<ul style="list-style-type: none"> <li>• Up to 100 kg: up to 15 vials per 42 days</li> <li>• Above 100 kg: up to 30 vials per 42 days</li> </ul>
Induction dose	High dose pediatric CD and UC	<ul style="list-style-type: none"> <li>• Up to 100 kg: up to 30 vials per 42 days</li> <li>• Above 100 kg: up to 60 vials per 42 days</li> </ul>



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Induction dose	Uveitis	<ul style="list-style-type: none"> <li>Up to 100 kg: up to 15 vials per 28 days</li> <li>Above 100 kg: up to 30 vials per 28 days</li> </ul>
Maintenance dose	High dose pediatric CD and UC/high dose pediatric UC transitioning into adulthood	<ul style="list-style-type: none"> <li>Up to 100 kg: up to 10 vials per 56 days</li> <li>Above 100 kg: up to 20 vials per 56 days</li> </ul>
Maintenance dose (not high dose or incomplete response)	CD/PsA/PsO/UC, above 100 kg	Up to 10 vials per 56 days
Maintenance dose (not high dose or incomplete response)	RA, above 100 kg	Up to 6 vials per 56 days
Maintenance dose (not high dose or incomplete response)	AS, above 100 kg	Up to 10 vials per 42 days
Maintenance dose	All other indications	<ul style="list-style-type: none"> <li>Up to 100 kg: up to 10 vials per 28 days</li> <li>Above 100 kg: up to 20 vials per 28 days</li> </ul>
Incomplete response	Adult/pediatric CD, adult/pediatric UC, PsA, PsO, and RA	<ul style="list-style-type: none"> <li>Up to 100 kg: up to 10 vials per 28 days</li> <li>Above 100 kg: up to 20 vials per 28 days</li> </ul>
Incomplete response	AS	<ul style="list-style-type: none"> <li>Up to 100 kg: up to 8 vials per 28 days</li> <li>Above 100 kg: up to 15 vials per 28 days</li> </ul>

FDA-recommended Dosing

Avsola, Inflectra, infliximab, Remicade, Renflexis



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#### Adult CD

- Intravenously 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks (starting at week 14).
- May increase the maintenance dose up to 10 mg/kg for loss of response.

#### Adult/pediatric UC, PsA, PsO, pediatric CD

- Intravenously 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks (starting at week 14).

#### RA

- Intravenously 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks, in combination with methotrexate (may increase the dose up to 10 mg/kg or treat as often as every 4 weeks).

#### AS

- Intravenously 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.

#### Zymfentra

##### Adult CD/UC

- Intravenously 5 mg/kg at 0, 2, and 6 weeks, then subcutaneously 120 mg every 2 weeks (starting at week 10)
- To switch patients from IV maintenance therapy, administer the first SC dose in place of the next scheduled infusion and every 2 weeks thereafter

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