Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Upadacitinib 45 mg extended-release (Rinvoq 45 mg ER)

Notes:

- Quantity Limits: Yes
- Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- *Per FDA approved dosing, upadacitinib 45 mg extended-release should only be used for 8 weeks (ulcerative colitis) or 12 weeks (Crohn's disease) as induction therapy. After the induction period, dose should be reduced to 15 mg or 30 mg once daily.

ULCERATIVE COLITIS:

<u>Initiation (new start) criteria:</u> Non-formulary **upadacitinib 45 mg extended-release** (**Rinvoq 45 mg ER**) will be covered on the prescription drug benefit for 8 weeks when the following criteria are met:

- Prescriber is a gastroenterologist and patient has a diagnosis of ulcerative colitis
- Patient has tried and failed/intolerant to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)

<u>Criteria for new members entering Kaiser Permanente already taking the</u> <u>medication who have not been reviewed previously:</u> Non-formulary **upadacitinib 45 mg extended-release (Rinvoq 45 mg ER)** will be covered on the prescription drug benefit for 4 weeks when the following criteria are met:

- Prescriber is a gastroenterologist and patient has a diagnosis of ulcerative colitis
- Patient has tried and failed/intolerant to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
- Duration of treatment with upadacitinib 45 mg extended-release tablets will not exceed 8 weeks*

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CROHN'S DISEASE:

Initiation (new start) criteria: Non-formulary **upadacitinib 45 mg extended-release** (**Rinvoq 45 mg ER**) will be covered on the prescription drug benefit for 12 weeks when the following criteria are met:

- Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease
 - Patient has tried and failed/intolerant to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)

<u>Criteria for new members entering Kaiser Permanente already taking the</u> <u>medication who have not been reviewed previously:</u> Non-formulary **upadacitinib 45** <u>mg extended-release (Rinvoq 45 mg ER)</u> will be covered on the prescription drug benefit for up to 8 weeks when the following criteria are met:

- Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease
- Patient has tried and failed/intolerant to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
- Duration of treatment with upadacitinib 45 mg extended-release tablets will not exceed 12 weeks*

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