Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE

Transmucosal immediate-release fentanyl products (TIRFs)

Notes:

- TIRF products are highly restricted by the FDA and currently unavailable for ordering or dispensing through KPNW ambulatory pharmacies. Prescribers and pharmacies must be certified and registered in the mandated Risk Evaluation and Mitigation Strategy (REMS) program and outpatients on therapy must be enrolled.**
- ^ Adequate trial is defined as 2 week treatment duration with titration as needed
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- †24-hour daily dose of at least 60 mg of oral morphine or 30 mg of oxycodone or 8 mg of hydromorphone or 25 mg of oxymorphone or 25 mcg/hr transdermal fentanyl
- ** As of 3/1/2021, no KPNW pharmacies are registered in the TIRF Access program. If a patient is determined to be eligible for therapy with a TIRF product, the pharmacy and pharmacists should contact Pharmacy Purchasing at NWSYSRXPurchasing@kp.org or 503-261-2037 for assistance with enrollment.

Initiation (new start) criteria: Non-formulary transmucosal immediate-release fentanyl products (brand or generics of Actiq, Fentora, Abstral, Lazanda, and Subsys) will be covered on the prescription drug benefit for 3 months when the following criteria are met:

- Pain is related to a cancer diagnosis
- Patient is 18 years of age or older (for Actiq 16 years or older)
- Patient is tolerant to around-the-clock opioid therapy equivalent to at least 60 mg of morphine†
- Patient has failed an adequate trial^ of or patient has an allergy or intolerance* to morphine immediate-release (IR), oxycodone IR and hydromorphone IR
- Prescriber is an Oncologist, Hospice/Palliative Care clinician for a patient currently enrolled in Hospice or Palliative Care program, or a Pain Management Specialist
- Patient has had an appointment with prescriber within prior 3 months
- REMS requirements have been met:
  1. Prescriber has completed training and enrollment in the TIRF REMS Access program.
  2. Dispensing pharmacy has registered and enrolled in the TIRF REMS Access program.
  3. Patient has been enrolled in the TIRF REMS Access program.

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Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary transmucosal immediate-release fentanyl products (brand or generics of Actiq, Fentora, Abstral, Lazanda, and Subsys) will be covered on the prescription drug benefit for 28 or 84 days when the following criteria are met:

- Since new enrollment in Kaiser Permanente, patient has upcoming referral or appointment with Oncologist, Hospice/Palliative Care clinician or Pain Management Specialist for pain management related to cancer diagnosis (may be covered on drug benefit for 28 days)
  -OR-
- Since new enrollment in Kaiser Permanente, patient has had appointment with Oncologist, Hospice/Palliative Care clinician or Pain Management Specialist for pain management related to cancer diagnosis (may be covered on drug benefit for 84 days)

- Pain is related to a cancer diagnosis
- Patient is 18 years of age or older (for Actiq 16 years or older)
- Patient is tolerant to around-the-clock opioid therapy equivalent to at least 60 mg of morphine†
- Patient has failed an adequate trial^ of or patient has an allergy or intolerance* to morphine immediate-release (IR), oxycodone IR and hydromorphone IR
- Prescriber is an Oncologist, Hospice/Palliative Care clinician for a patient currently enrolled in Hospice or Palliative Care program, or a Pain Management Specialist
- REMS requirements have been met:
  1. Prescriber has completed training and enrollment in the TIRF REMS Access program.
  2. Dispensing pharmacy has registered and enrolled in the TIRF REMS Access program.
  3. Patient has been enrolled in the TIRF REMS Access program.

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For additional prescriptions (beyond 28 days), *new members* entering Kaiser Permanente already taking the medication: Non-formulary transmucosal immediate-release fentanyl products (brand or generics of Actiq, Fentora, Abstral, Lazanda, and Subsys) will be covered on the prescription drug benefit for 84 days when the following criteria are met:

- Since new enrollment in Kaiser Permanente, patient has had appointment with Oncologist, Hospice/Palliative Care clinician or Pain Management Specialist for pain management related to cancer diagnosis
- Pain is related to a cancer diagnosis
- Patient is 18 years of age or older (for Actiq 16 years or older)
- Patient is tolerant to around-the-clock opioid therapy equivalent to at least 60 mg of morphine†
- Patient has failed an adequate trial^ of or patient has an allergy or intolerance* to morphine immediate-release (IR), oxycodone IR and hydromorphone IR
- Prescriber is an Oncologist, Hospice/Palliative Care clinician for a patient currently enrolled in Hospice or Palliative Care program, or a Pain Management Specialist
- REMS requirements have been met:
  1. Prescriber has completed training and enrollment in the TIRF REMS Access program.
  2. Dispensing pharmacy has registered and enrolled in the TIRF REMS Access program.
  3. Patient has been enrolled in the TIRF REMS Access program.

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Transmucosal immediate-release fentanyl products (TIRFs)

Continued use criteria (3 months after initiation and for patients stable on the medication): Non-formulary transmucosal immediate-release fentanyl products (brand or generics of Actiq, Fentora, Abstral, Lazanda, and Subsys) will continue to be covered on the prescription drug benefit for 3 months when the following criteria are met:

- Pain is related to a cancer diagnosis
- Patient is 18 years of age or older (for Actiq 16 years or older)
- Patient is tolerant to around-the-clock opioid therapy equivalent to at least 60 mg of morphine†
- Patient has failed an adequate trial^ of or patient has an allergy or intolerance* to morphine immediate-release (IR), oxycodone IR and hydromorphone IR
- Prescriber is an Oncologist, Hospice/Palliative Care clinician for a patient currently enrolled in Hospice or Palliative Care program, or a Pain Management Specialist
- Patient has had an appointment with prescriber within prior 3 months
- REMS requirements have been met:
  1. Prescriber has completed training and enrollment in the TIRF REMS Access program.
  2. Dispensing pharmacy has registered and enrolled in the TIRF REMS Access program.
  3. Patient has been enrolled in the TIRF REMS Access program.