Fentanyl Agents
Clinical Edit Criteria

Drug/Drug Class:

Fentanyl Agents
Superior HealthPlan follows the guidance of the Texas Vendor Drug Program (VDP) for all clinical edit criteria. Superior has adjusted the clinical criteria to ease the prior authorization process regarding this clinical edit. Changes to the original edit are noted in yellow highlight within this document. Fentora criteria has been shortened as steps 4-13 from the original criteria have been removed.

The original clinical edit can be referenced at the VDP website located at https://www.txvendordrug.com/formulary/prior-authorization/mco-clinical-pa.

Clinical Edit Information Included in this Document:
Abstral (Fentanyl Sublingual Tablet) / Lazanda (Fentanyl Nasal Spray) / Subsys (Fentanyl Sublingual Spray)
Actiq (Oral Transmucosal Fentanyl)
Duragesic (Transdermal Fentanyl)
Fentora (Buccal Fentanyl)

- Drugs requiring prior authorization: the list of drugs requiring prior authorization for this clinical criteria.
- Prior authorization criteria logic: a description of how the prior authorization request will be evaluated against the clinical criteria rules.
- Logic diagram: a visual depiction of the clinical edit criteria logic.
- Diagnosis codes or drugs in step logic: a list of diagnosis codes or drug information and additional step logic, claims and lookback period information.
- Supporting tables: a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable. The supporting tables by VDP are so large that a cross reference has been provided to the original VDP edit as Superior implements the VDP’s logic inside these tables.
- Clinical edit references: clinical edit references as provided by the Texas Vendor Drug Program.
- Publication history: to track when the eased criteria was put into production and any updates since this time.

Please note: All tables are provided by original VDP Edit.
Drugs Requiring Prior Authorization Abstral / Lazanda / Subsys:

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<tr>
<th>Label Name</th>
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<tr>
<td>ABSTRAL 100MCG SUBLINGUAL TABLETS</td>
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<td>ABSTRAL 200MCG SUBLINGUAL TABLETS</td>
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<td>SUBSYS 800MCG SPRAY</td>
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</table>
Superior HealthPlan Clinical Criteria Logic Abstract / Lazanda / Subsys:

1. Is the client ≥ 18 years of age?
   [ ] Yes (Go to #2)
   [ ] No (Deny)

2. Does the client have a diagnosis of malignancy in the last 730 days?
   [ ] Yes (Go to #4)
   [ ] No (Go to #3)

3. Does the client have a history of antineoplastic therapy in the last 365 days?
   [ ] Yes (Go to #4)
   [ ] No (Deny)

4. Does the client have a claim for a long-acting opioid analgesic in the last 30 days?
   [ ] Yes (Go to #5)
   [ ] No (Deny)

5. Does the patient have a claim for an MAOI or CYP3A4 inhibitor in the last 30 days?
   [ ] Yes (Deny)
   [ ] No (Go to #6)

6. Is the total daily dose less than or equal to (≤) 3200mcg?
   [ ] Yes (Approve – 365)
   [ ] No (Deny)
Superior HealthPlan Clinical Edit Logic Diagram Abstral / Lazanda / Subsys:

**Step 1**
Is the client ≥ 18 years of age?

- **No** → Deny
- **Yes**

**Step 2**
Does the client have a diagnosis of a malignancy in the last 730 days?

- **Yes**
  - **Yes**
    - **Yes** → Deny
    - **No** → **Step 3**
  - **No** → **Step 4**

**Step 3**
Does the client have a history of an antineoplastic agent in the last 365 days?

- **No** → **Step 2**
- **Yes** → Deny

**Step 4**
Does the client have a claim for a long-acting opioid analgesic in the last 30 days?

- **No** → Deny
- **Yes**

**Step 5**
Does the client have a claim for an MAOI or CYP3A4 inhibitor in the last 30 days?

- **No** → Deny
- **Yes**

**Step 6**
Is the total daily dose ≤ 3200mcg?

- **Yes** → Approve (365 days)
- **No** → Deny

Deny
Drugs Requiring Prior Authorization Actiq (Transmucosal Fentanyl):

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<td>FENTANYL CITRATE OTFC 800 MCG</td>
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Superior HealthPlan Clinical Criteria Logic Actiq (Transmucosal Fentanyl)

1. Is the client less than (<) 16 years of age?
   [ ] Yes (Deny)
   [ ] No (Go to #2)

2. Does the client have a diagnosis of cancer or fibrotic lung disease in the last 730 days?
   [ ] Yes (Go to #5)
   [ ] No (Go to #3)

3. Does the client have a history of antineoplastic therapy in the last 365 days?
   [ ] Yes (Go to #5)
   [ ] No (Go to #4)

4. Does the client have a diagnosis of CNMP in the last 365 days?
   [ ] Yes (Go to #5)
   [ ] No (Deny)

5. Does the client have less than or equal to (≤) 7 days of opioid therapy in the last 30 days?
   [ ] Yes (Deny)
   [ ] No (Go to #6)

6. Does the client have a claim for an MAOI or a strong/moderate CYP3A4 inhibitor in the last 30 days?
   [ ] Yes (Deny)
   [ ] No (Go to #7)

7. Is the request for transmucosal fentanyl 200mcg?
   [ ] Yes (Go to #10)
   [ ] No (Go to #8)

8. Is the request for transmucosal fentanyl greater than or equal to (≥) 400mcg?
   [ ] Yes (Go to #9)
   [ ] No (Deny)

9. Does the client have a history of transmucosal fentanyl therapy in the last 30 days with the dose greater than or equal to (≥) 200mcg?
   [ ] Yes (Go to #10)
   [ ] No (Deny)

10. Is the request for less than or equal to (≤) 4 units per day?
    [ ] Yes (Approve – 365 days)
    [ ] No (Deny)
Superior HealthPlan Clinical Edit Logic Diagram Actiq (Transmucosal Fentanyl):

1. **Step 1**
   - Is the client < 16 years of age?
   - **Yes**: Deny
   - **No**: Continue

2. **Step 2**
   - Does the client have a diagnosis of cancer or fibrotic lung disease in the last 730 days?
   - **Yes**: Deny
   - **No**: Continue

3. **Step 3**
   - Does the client have a history of an antiemetic agent in the last 365 days?
   - **Yes**: Deny
   - **No**: Continue

4. **Step 4**
   - Does the client have a diagnosis of CMNP in the last 365 days?
   - **Yes**: Deny
   - **No**: Continue

5. **Step 5**
   - Does the client have ≤ 7 days opioid therapy in the last 30 days?
   - **Yes**: Deny
   - **No**: Continue

6. **Step 6**
   - Does the client have a claim for an MAOI or a strong/moderate CYP3A4 inhibitor in the last 30 days?
   - **Yes**: Deny
   - **No**: Continue

7. **Step 7**
   - Is the request for transmucosal fentanyl 200 mcg?
   - **Yes**: Deny
   - **No**: Continue

8. **Step 8**
   - Is the request for transmucosal fentanyl ≥ 400 mcg?
   - **Yes**: Deny
   - **No**: Continue

9. **Step 9**
   - Does the client have a history of transmucosal fentanyl therapy in the last 30 days with the dose ≥ 200 mcg?
   - **Yes**: Deny
   - **No**: Continue

10. **Step 10**
    - Is the request for ≤ 4 units/day?
    - **Yes**: Deny
    - **No**: Approve (365 days)
Drugs Requiring Prior Authorization Duragesic (Transdermal Fentanyl):

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Superior HealthPlan Clinical Criteria Logic Duragesic (Transdermal Fentanyl):

1. Does the client have a diagnosis of cancer or fibrotic lung disease in the last 730 days?
   [ ] Yes (Go to #6)
   [ ] No (Go to #2)

2. Does the client have a history of an antineoplastic agent in the last 365 days?
   [ ] Yes (Go to #6)
   [ ] No (Go to #3)

3. Does the client have less than or equal to (≤) 7 days of opioid therapy in the last 30 days?
   [ ] Yes (Go to #4)
   [ ] No (Go to #6)

4. Does the client have a diagnosis of chronic non-malignant pain in the last 365 days?
   [ ] Yes (Go to #6)
   [ ] No (Go to #5)

5. Does the client have a history of an inferring CNMP non-opioid analgesic for less than or equal to (≤) 60 days out of the last 90 days?
   [ ] Yes (Deny)
   [ ] No (Go to #6)

6. Is the dose less than or equal to (≤) 25ug per hour?
   [ ] Yes (Go to #8)
   [ ] No (Go to #7)

7. Does the client have less than or equal to (≤) 14 days of opioid therapy in the last 30 days?
   [ ] Yes (Deny)
   [ ] No (Go to #8)

8. Is the dose less than or equal to (≤) 600ug per hour?
   [ ] Yes (Approve – 365 days)
   [ ] No (Deny)
Superior HealthPlan Clinical Edit Logic Duragesic (Transdermal Fentanyl):

[Flowchart diagram with decision points and outcomes indicated]

- Step 1: Does the client have a diagnosis of cancer or metastatic disease in the last 56 days? (No/Yes)
- Step 2: Does the client have a history of an opioid-ergic agent in the last 365 days? (No/Yes)
- Step 3: Does the client have a history of nausea in the last 365 days? (No/Yes)
- Step 4: Does the client have a history of chronic non-malignant pain in the last 365 days? (No/Yes)
- Step 5: Does the client have a history of an opioid-ergic agent in the last 90 days out of the last 90 days? (No/Yes)
- Step 6: Is the dose ≤ 25 μg per hour? (No/Yes)
- Step 7: Does the client have a 14-day supply of opioid therapy in the last 30 days? (No/Yes)
- Step 8: Is the dose ≤ 600 μg per hour? (No/Yes)

Decision Outcomes:
- Deny Request
- Approve Request (90 days)
Drugs Requiring Prior Authorization Fentora (Buccal Fentanyl):

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<tr>
<td>FENTORA 800 MCG BUCCAL TABLET</td>
<td>97285</td>
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Superior HealthPlan Clinical Criteria Logic Fentora (Buccal Fentanyl):

1. Is the client greater than or equal to (≥) 18 years of age?
   - [ ] Yes (Go to #2)
   - [ ] No (Deny)

2. Does the client have a diagnosis of malignant cancer in the last 730 days?
   - [ ] Yes (Approve – 365 days)
   - [ ] No (Go to #3)

3. Does the client have a history of an antineoplastic agent in the last 365 days?
   - [ ] Yes (Approve – 365 days)
   - [ ] No (Deny)

4. Does the client have a claim for an MAOI or CYP3A4 inhibitor in the last 30 days?
   - [ ] Yes (Deny)
   - [ ] No (Go to #5)

5. Does the client have at least 12 days supply of opioid therapy in the last 14 days?
   - [ ] Yes (Go to #6)
   - [ ] No (Deny)

6. Does the client have a history of buccal fentanyl in the last 35 days?
   - [ ] Yes (Go to #13)
   - [ ] No (Go to #7)

7. Does the client have a history of opioid tolerance with defined oral morphine, transdermal fentanyl, oxycodone, hydromorphone, OR oxymorphone therapy in the last 30 days?
   - [ ] Yes (Go to #8)
   - [ ] No (Deny)

8. Is the request for buccal fentanyl 100mcg?
   - [ ] Yes (Go to #13)
   - [ ] No (Go to #9)

9. Is the request for buccal fentanyl 200mcg?
   - [ ] Yes (Go to #10)
   - [ ] No (Go to #11)

10. Does the client have a claim for Actiq 600, 800, 1200 or 1600mcg in the last 35 days?
    - [ ] Yes (Go to #13)
11. Is the request for buccal fentanyl 400mcg?
   [ ] Yes (Go to #12)
   [ ] No (Deny)

12. Does the client have a history of Actiq 1200 or 1600mcg in the last 35 days?
   [ ] Yes (Go to #13)
   [ ] No (Deny)

13. Is the request for less than or equal to (≤) 4 units/day?
   [ ] Yes (Approve – 365 days)
   [ ] No (Deny)
Superior HealthPlan Clinical Edit Logic Fentora (Buccal Fentanyl):

Is the client greater than or equal to (≥) 18 years of age?

Yes

Does the client have a diagnosis of malignant cancer in the last 730 days?

Yes

Approve 365

No

Does the client have a diagnosis of malignant cancer in the last 730 days?

Yes

Approve 365

No

Does the client have a history of an antineoplastic agent in the last 365 days?

Yes

Approve 365

No

Deny
Clinical Criteria Supporting Tables Fentanyl Agents:

Due to the size of the supporting tables provided by Texas Vendor Drug Program please reference https://paxpress.txpa.hidinc.com/fentanyl.pdf for all supporting table documentation.
Clinical Criteria References:


### Publication History:

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<th>Notes</th>
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<td>11/5/18</td>
<td>Criteria created and cross referenced to VDP criteria.</td>
</tr>
<tr>
<td>2/7/19</td>
<td>Added Fentora criteria and cross referenced to VDP criteria</td>
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