

PROGRAM: ORAL /INTRANASAL FENTANYL PRODUCTS DESCRIPTION

The purpose of this document is to provide approval criteria and guidelines for prior authorization of benefits (PAB) of Oral /Intranasal Fentanyl Products. Oral/Intranasal Fentanyl products are used for the treatment of pain associated with cancer. Claims submitted without obtaining prior authorization of benefits will reject on the pharmacy claim system.

The Oral/ /Intranasal Fentanyl Products are subject to quantity limits and will only be approved for the dosing limit that is supported by the FDA for the approved indication, and as approved by the BCBSRI Pharmacy and Therapeutics Committee. Quantity limits within specific prior authorization of benefits guidelines supersede the Quantity Supply Program Policy. Requests for quantities greater than the quantity limit will be reviewed for medical necessity.

APPLICABLE LINES OF BUSINESS

Managed Plans

FORMULARY

Abstral

Actiq

Fentora

Lazanda

Onsolis

APPROVAL DURATION AND QUANTITY LIMITS

Approval Duration: 6 months

Quantity Limit:

Abstral, Actiq, Fentora, Onsolis: 120 lozenges per 25 days or 360 lozenges per 75 days

Lazanda: 8 bottles per 25 days or 23 bottles per 75 days

APPROVAL CRITERIA

Patient must meet all of the following criteria:

I. Patient is 18 years of age or older, or if Actiq is the drug requested, the patient is 16 years of age or older

AND

II. Patient is being managed with the requested oral/intranasal fentanyl agent for breakthrough pain due to current cancer condition or cancer related complication

AND

III. A long-acting opioid is being prescribed for around-the-clock treatment of the cancer pain

AND

IV. The prescriber has evaluated the patient's risk for serious opioid adverse events (i.e., respiratory depression/sedation) before prescribing the requested opioid narcotic

AND

V. Patient is not taking a strong or moderate cytochrome P450 3A4 inhibitor(s) (e.g., ritonavir, ketoconazole, itraconazole, clarithromycin, nelfinavir, nefazodone, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, or verapamil)

OR

VI. Patient is being carefully monitored and dosage adjustments are made when necessary if the patient is taking a strong or moderate cytochrome P450 3A4 inhibitor(s) (e.g., ritonavir, ketoconazole, itraconazole, clarithromycin, nelfinavir, nefazodone, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, or verapamil)

LOOK BACK CRITERIA IN CLAIMS SYSTEM

Not applicable