Pharmacy Policy Bulletin

Title: Iloperidone (Fanapt™)

Policy #: Rx.01.42

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

Iloperidone(Fanapt™) is indicated for the acute treatment of schizophrenia in adults.

The use of Iloperidone(Fanapt™) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:

Iloperidone (Fanapt™) is an atypical antipsychotic agent whose mechanism of action is unknown. It is proposed that the efficacy is mediated through a combination of dopamine type 2 (D2) and serotonin type 2 (5-HT2) antagonisms.

Policy:

Iloperidone(Fanapt™) is approved when **one** of the following inclusion criteria is met:

- Documentation of diagnosis of schizophrenia and documentation of a trial and failure of, or contraindication to, at least **one** of the following medications:
  - Aripiprazole (Abilify®)
  - Risperidone (Risperdal®)
  - Quetiapine fumarate (Seroquel®)
  - An olanzapine-containing product
- Documentation of diagnosis of schizophrenia and documentation of stabilization from an institutional setting
- Documentation of diagnosis of schizophrenia and documentation of current stabilization for over four weeks with corresponding dates

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Fanapt™ (Iloperidone) [package insert]. Rockville, MD:Vanda Pharmaceuticals; August 2010.

Iloperidone(Fanapt™). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed September 12, 2011.

Iloperidone(Fanapt™). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed September 12, 2011.

Cutler AJ, Kalali AH, Weiden PJ, et al: Four-week, double-blind, placebo- and ziprasidone-controlled trial of iloperidone in patients with acute exacerbations of schizophrenia. J Clin Psychopharmacol 2008; 28(2 Suppl 1):S20-S28.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Fanapt	iloperidone

Cross References:

Policy Version Number:	1.00
P&T Approval Date:	July 14, 2011
Policy Effective Date:	October 01, 2011
Next Required Review Date:	July 14, 2012