

VALLEYCARE
OLIVE VIEW-UCLA MEDICAL CENTER/HEALTH CENTERS
POLICY & PROCEDURE

NUMBER: 1590
VERSION: 1

SUBJECT/TITLE: **BLACK BOX WARNING**

POLICY: ValleyCare’s Pharmacy and Pharmacy & Therapeutics Committee provide system wide education and promotion of the safe uses of Black Box Warning (BBW) medications

PURPOSE: To promote the safe use of BBW medications

DEPARTMENTS: All

DEFINITIONS: **Black Box Warning:** This warning generally appears at the top of the product prescribing information and is characterized by the surrounding black border. The “Black Box Warning” represents the strongest warning issued by the Food and Drug Administration (FDA). This means that the FDA has determined that the medication carries a significant risk of serious or even life-threatening adverse effects.

PROCEDURE:

- A. Both the DHS P&T Committee and the ValleyCare P&T Committee focus on drug safety information. BBW that have been identified by the FDA and Institute for Safe Medication Practice (ISMP) as posing a high risk of patient harm are reviewed in the Committees. The ValleyCare P&T Committee will establish facility policy as appropriate for specific medications.
- B. The P&T Committee distributes the information via Intranet postings, meeting discussions, e-mails and bulletins to appropriate prescribers and clinicians. For example, a Black Box Warning for a cancer chemotherapy agent will be forwarded to the Hematology/Oncology P&T representative. It is the responsibility of this representative to further distribute this information to physicians in his/her department.
- C. Nurses are alerted in the Pyxis system of DHS priority Black Box Warnings when accessing these medications.
- D. The list of Black Box Warning Medications with information and recommendations for nurses/pharmacists/prescribers is available on the Intranet and is updated as needed.
- E. Certain Black Box Warning Medications may require specific prescribing restrictions (for example, fentanyl patch requires an order form;

SUBJECT/TITLE: BLACK BOX WARNING

Policy Number: 1590

Page Number: 2

haldoperidol IV requires EKG monitoring, etc.). Such prescribing restrictions will be determined and approved by the ValleyCare P&T Committee.

References: Evidence-based Review of the Black-box Warning for Droperidol: Discussion. American Journal of Health-System Pharmacy. 2007;64(11):1174-1186.	
Approved by: OVEC-2018 October	Date: 06/24/2011
Review Date: 07/25/2017	Revision Date:
Distribution: Olive View Hospital-Wide Policies	
Original Date: 06/24/2011	