

ISSUE DATE December 29, 2014	EFFECTIVE DATE December 9, 2014	NUMBER *See below
SUBJECT Prior Authorization of Hepatitis C Agents - Pharmacy Services		BY  Vincent D. Gordon, Deputy Secretary Office of Medical Assistance Programs

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department of Public Welfare will require prior authorization of all Hepatitis C Virus (HCV) Direct Acting Antivirals.
2. Issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Hepatitis C Agents, including the type of medical information needed to evaluate requests for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

During the March 25, 2014 meeting, the Department's Drug Utilization Review (DUR) Board DUR Board recommended that the Department require prior authorization of sofosbuvir (Solvaldi) and simeprevir (Olysio). While both drugs were described as breakthrough hepatitis C treatments, the Board recognized that medically-accepted standards of care were still evolving, and the cost was generating significant discussion and debate nationwide.

*01-14-53	09-14-46	27-14-44	33-14-45
02-14-43	11-14-43	30-14-43	
03-14-46	14-14-43	31-14-50	
08-14-47	24-14-44	32-14-43	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dpw.state.pa.us/provider/healthcaremedicalassistance/index.htm>

DISCUSSION:

New therapies that offer simpler, all oral regimens are in various stages of clinical development or approval by the Food and Drug Administration (FDA). The medically accepted standards of care continue to evolve, and price continues to generate debate. In response to the recent FDA approval of Harvoni (ledipasvir/sofosbuvir), and consistent with the most recent recommendations of the DUR Board, the Department is updating the guidelines to determine medical necessity of HCV Direct Acting Antivirals. Department clinical pharmacists and medical directors conferred with several medical specialists prior to updating the guidelines to determine medical necessity of Hepatitis C Agents, which were then subject to public review and comment. The guidelines will be reviewed by the DUR Board at the next public Board meeting. In the interim, the requirements for prior authorization and clinical review guidelines to determine the medical necessity of Hepatitis C Agents are included in the attached updated provider handbook pages.

PROCEDURE:

The procedures for prescribers to request prior authorization of Hepatitis C Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapters related to Hepatitis C Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Hepatitis C Agents