

ISSUE DATE November 10, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *See below
SUBJECT Prior Authorization of Intra-Articular Hyaluronates – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Intra-Articular Hyaluronates submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Intra-Articular Hyaluronates will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Intra-Articular Hyaluronates to the appropriate managed care organization.

*01-20-32	09-20-31	27-20-27	33-20-28
02-20-25	11-20-25	30-20-24	
03-20-25	14-20-26	31-20-32	
08-20-35	24-20-25	32-20-24	

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 website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the August 12, 2020, meeting, the P&T Committee recommended a revision to the guidelines to determine medical necessity of Intra-Articular Hyaluronates to allow for approval of treatment for both knees upon an initial request.

The revisions to the guidelines to determine medical necessity of Intra-Articular Hyaluronates, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Intra-Articular Hyaluronates 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 chapter related to Intra-Articular Hyaluronates) 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

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Intra-Articular Hyaluronates

A. Prescriptions That Require Prior Authorization

All prescriptions for Intra-Articular Hyaluronates must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Intra-Articular Hyaluronate, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Intra-Articular Hyaluronate for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication; **AND**
2. Has a documented history of therapeutic failure, contraindication, or intolerance to **all** of the following:
 - a. Non-pharmacologic treatments,
 - b. Acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs),
 - c. Intra-articular glucocorticoid injection;

AND

3. Does not have a contraindication to the requested agent; **AND**
4. For a non-preferred Intra-Articular Hyaluronate, has a history of therapeutic failure, contraindication, or intolerance of the preferred Intra-Articular Hyaluronates. See the Preferred Drug List (PDL) for the list of preferred Intra-Articular Hyaluronates at: <https://papdl.com/preferred-drug-list>; **AND**
5. If a prescription for an Intra-Articular Hyaluronate is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR INTRA-ARTICULAR HYALURONATES:
The determination of medical necessity of a request for renewal of a prior authorization for an

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

Intra-Articular Hyaluronate that was previously approved will take into account whether the beneficiary:

1. Has documented improvement in pain or joint function following the first treatment; **AND**
2. Did not receive an Intra-Articular Hyaluronate in the same joint within the past 6 months; **AND**
3. Does not have a contraindication to the requested agent; **AND**
4. If a prescription for an Intra-Articular Hyaluronate is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Intra-Articular Hyaluronate. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

C. Revisions to Dose and Duration of Therapy

Requests for prior authorization of an Intra-Articular Hyaluronate will be approved for one treatment course per knee.

D. References

1. Hochberg, M.C. et.al, American College of Rheumatology 2012.
2. Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee. Arthritis Care & Research. 64(4), April 2012, 465–474.
3. Fernandes, L. et.al, EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. Ann Rheum Dis doi:10.1136/annrheumdis-2012-202745. Published Online First 17 April 2013.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

4. Jordan, K.M. et.al, EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT) Ann Rheum Dis, Publish Online First: 21 July 2003; 62: 1145 - 1155.
5. McAlindon, T.E. et.al, OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis and Cartilage 22 (2014) 363e388.
6. Kalunian, K.C et.al, Initial pharmacologic therapy of osteoarthritis UpToDate accessed 1/26/15.
7. Kalunian, K.C et.al, Treatment of osteoarthritis resistant to initial pharmacologic therapy. UpToDate accessed 1/26/15.
8. Euflexxa prescribing information. Ferring Pharmaceuticals Inc. September 2011.
9. Gel-One prescribing information. Zimmer, Inc; May 2011.
10. Hyalgan prescribing information. Fidia Pharma USA Inc. October 2013.
11. Orthovisc prescribing information. Anika Therapeutics, Inc.
12. Supartz prescribing information. Bioventus LLC. June 2012.
13. Synvisc prescribing information. Genzyme Biosurgery. September 2014.
14. Synvisc One prescribing information. Genzyme Biosurgery. September 2014.