Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2305898
Decision Date:	09/25/2023	**Hearing Date:**	8/24/2023
Hearing Officer:	Sara E. McGrath		

Appearances for Appellant:

[redacted]

Interpreter:
Zully Rodriguez

Appearances for MassHealth:
Phuong Luc, Pharm.D., R.Ph.

Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
Board of Hearings
100 Hancock Street
Quincy, MA 02171

APPEAL DECISION

Appeal Decision:	Denied	**Issue:**	Prior Authorization (Drug utilization Review)
Decision Date:	09/25/20223	**Hearing Date:**	8/24/2023
MassHealth Rep.:	Phuong Luc, Pharm.D., R.Ph.	**Appellant Rep.:**	Pro se
Hearing Location:	Board of Hearings (Remote)	**Aid Pending:**	No

Authority

This hearing was conducted pursuant to Massachusetts General Laws Chapter 118E, Chapter 30A, and the rules and regulations promulgated thereunder.

Jurisdiction

Through a notice dated July 7, 2023, MassHealth denied the appellant's request for prior authorization for the prescription drug Durolane (130 CMR 406.413(E)(8)). The appellant filed a timely appeal on July 19, 2023. Denial of prior authorization is valid grounds for appeal (130 CMR 610.032). At the conclusion of the hearing, the record was held open until September 7, 2023 to allow the appellant to submit additional evidence, and until September 21, 2023 for MassHealth to review and respond.

Action Taken by MassHealth

MassHealth denied the appellant's prior authorization request for Durolane because it determined that the appellant did not demonstrate that the requested drug is medically necessary.

Issue

The appeal issue is whether the appellant has demonstrated the medical necessity of the requested drug.

Summary of Evidence

A registered pharmacist from the MassHealth Drug Utilization Review (DUR) program testified telephonically and explained that on July 7, 2023, the appellant's provider submitted a prior authorization (PA) request on the appellant's behalf for Durolane, a single-injection hyaluronic acid treatment for knee osteoarthritis. The appellant's provider indicated that the appellant has a diagnosis of right knee osteoarthritis (Exhibit 3, p. 4). The provider indicated that the appellant tried acetaminophen and ibuprofen in 2022, and tried an intra-articular corticosteroid injection several times (mostly recently on June 5, 2023) – all with an inadequate response and insufficient relief (Exhibit 3, pp. 4-5). On July 7, 2023, MassHealth denied the request with the following comment:

> Your prior authorization request for HYALURONAN OR DERIVATIVE, INTRA-ART INJ is denied. Information provided did not contain sufficient information to determine medical necessity. Prescriber may resubmit a new prior authorization request with additional clinical documentation (e.g. diagnosis, specific joints to be treated, previous drug trials with drug name, dates and duration of use). Additional information regarding the MassHealth Drug List and specific prior authorization forms can be found at www.mass.gov/druglist (Exhibit 3, p. 28).

The DUR pharmacist referenced the MassHealth Drug List (MHDL), which is a list that specifies which drugs need PA when prescribed for MassHealth members. The PA requirements specified in the MHDL reflect MassHealth's policy described in the pharmacy regulations and other communications from MassHealth, as well as MassHealth's and the DUR Board's review of drugs within certain therapeutic classes. The MHDL Therapeutic Tables provide a view of drugs within their respective therapeutic classes, along with PA requirements, clinical information about the drug, and evaluation criteria for prior authorization for select therapeutic classes. The criteria for prior authorization identify the clinical information MassHealth considers when determining medical necessity for selected medications. The criteria are based upon generally accepted standards of practice, review of the medical literature, federal and state policies, as well as laws applicable to the Massachusetts Medicaid Program.

The DUR pharmacist testified that Durolane is a brand-name hyaluronan injection. MHDL Therapeutic Table 77 sets forth the PA requirements for this medication, as follows:

Documentation of all of the following is required:

- appropriate diagnosis; **and**

- inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to acetaminophen; **and**
- inadequate response or adverse reaction to one or contraindication to all intra-articular corticosteroid injections; **and**
- inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all nonsteroidal anti-inflammatory drug (NSAIDs).

(Exhibit 3, p. 38).

The DUR pharmacist explained that the appellant has not documented an inadequate response or adverse reaction to either acetaminophen or an NSAID. Specifically, the appellant did not document at least 30 days of therapy with either acetaminophen or ibuprofen. The provider documented only that the appellant tried both drugs in 2022. Without more specificity regarding the length of each drug trial, the appellant did not meet the requirements for approval.

MassHealth referenced an August 9, 2023 letter it sent to the appellant requesting additional information (Exhibit 3, p. 30). The letter requested documentation that the appellant has tried acetaminophen and an NSAID for at least 30 days, and they did not work or that she had unacceptable side effects. Because MassHealth did not receive a response to its letter, the denial remained in place.

The appellant testified telephonically, and explained that she trialed acetaminophen and ibuprofen for at least 30 days, without relief. The hearing officer left the record open to allow the appellant to submit documentation from her provider confirming the specific dates of the drug trials. The appellant did not submit any additional documentation during the record-open period (Exhibit 4).

Findings of Fact

Based on a preponderance of the evidence, I find the following facts:

1. On July 7, 2023, the appellant's provider submitted a PA request on the appellant's behalf for Durolane.
2. Durolane is a brand-name hyaluronan injection treatment for knee osteoarthritis.
3. The appellant has a diagnosis of right knee osteoarthritis.
4. Durolane requires PA and requires documentation of the following:
    - appropriate diagnosis; **and**

- inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to acetaminophen; **and**
- inadequate response or adverse reaction to one or contraindication to all intra-articular corticosteroid injections; **and**
- inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all nonsteroidal anti-inflammatory drug (NSAIDs).

5. The appellant did not submit documentary evidence of a 30-day trial of acetaminophen or an NSAID.

6. On July 7, 2023, MassHealth denied appellant's request for prior authorization.

7. On July 19, 2023, the appellant timely appealed MassHealth's determination.

Analysis and Conclusions of Law

MassHealth covers pharmacy services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations (130 CMR 406.403). Under 130 CMR 406.422, prescribers must obtain prior authorization from MassHealth for drugs identified by MassHealth in accordance with 130 CMR 450.303. In addition, this regulation states that if the limitations on covered drugs specified in 130 CMR 406.412(A) and 406.413(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to MassHealth for prior authorization for an otherwise noncovered drug or medical supply. Medical necessity is defined as follows:

> A service is medically necessary if
>
> (1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and
> (2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency. Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior-authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007: *Potential Sources of Health Care*, or 517.007: *Utilization of Potential Benefits*.

(130 CMR 450.204(A)).

As noted above, the MHDL provides sub-regulatory guidance and its requirements reflect MassHealth's policy described in the pharmacy regulations and other communications from MassHealth, as well as MassHealth's and the DUR Board's review of drugs within certain therapeutic classes. The MHDL Therapeutic Table 77 sets forth the PA requirements for Durolane, and those requirements include evidence of a 30-day trial of both acetaminophen and an NSAID. The appellant testified to a 30-day trial of both drugs, but did not submit sufficient documentation to verify these trials.[1] Without this documentation, the appellant has not satisfied MassHealth's PA requirements and thus has not demonstrated that Durolane is a medical necessity at this time.

MassHealth correctly denied the appellant's request for prior authorization. This appeal is denied.

Order for MassHealth

None.

Notification of Your Right to Appeal to Court

If you disagree with this decision, you have the right to appeal to Court in accordance with Chapter 30A of the Massachusetts General Laws. To appeal, you must file a complaint with the Superior Court for the county where you reside, or Suffolk County Superior Court, within 30 days of your receipt of this decision.

Sara E. McGrath
Hearing Officer
Board of Hearings

cc: MassHealth Drug Utilization Review Program

[1] The appellant's submission includes some of her medical records – these records do not reference the appellant's use of acetaminophen or an NSAID (Exhibit 3, pp. 7-26).