Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2202463
Decision Date:	8/16/2022	**Hearing Date:**	06/14/2022
Hearing Officer:	Paul C. Moore	**Record Closed:**	07/26/2022

Appellant Representative:
Pro se (by telephone)

MassHealth Representative:
Meghan Serell, Pharm.D., R.Ph., MassHealth Drug Utilization Program (by telephone)

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

APPEAL DECISION

Appeal Decision:	Denied	**Issue:**	Prior Authorization, Drug Utilization Review
Decision Date:	8/16/2022	**Hearing Date:**	06/14/2022
MassHealth Rep.:	Dr. Serell	**Appellant Rep.:**	Pro se
Hearing Location:	Board of Hearings (remote)		

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 March 10, 2022, MassHealth denied the appellant's prior authorization (PA) request for oxycodone HCL (immediate-release) 30 mg. tablets (one tablet three times a day) because the PA request did not contain sufficient information to determine medical necessity (Exh. 1). The appellant filed this appeal with the Board of Hearings (BOH) in a timely manner on March 25, 2022 (130 CMR 610.015(B)(1); Exh. 2). Denial of PA is a valid ground for appeal (130 CMR 610.032).

A telephonic hearing was originally scheduled for May 4, 2022 (Exh. 6). The appellant did not appear for that hearing, and BOH dismissed the appeal by letter to the appellant dated May 9, 2022 (Exh. 7). On May 19, 2022, the appellant sent a letter to BOH explaining that she had never received notice of the hearing, and that she had been scheduled for surgery in late April, 2022 (Exh. 8). The BOH vacated the dismissal, and set a new hearing date of June 14, 2022 (Exh. 5).

Following the June 14, 2022 hearing, the hearing record was left open until July 26, 2022 for the appellant and the MassHealth representative to exchange additional documentation.

Action Taken by MassHealth

MassHealth denied the appellant's PA request for oxycodone HCL (immediate-release) 30 mg. tablets (one tablet three times a day).

Issue

The appeal issue is whether MassHealth was correct in denying the appellant's PA request for oxycodone HCL (immediate-release) 30 mg. tablets (one tablet three times a day).

Summary of Evidence

The MassHealth representative, a doctor of pharmacy and a licensed pharmacist, testified by telephone that oxycodone HCL immediate-release (IR) is a short-acting opioid analgesic used for pain management. For doses of 80 mg. per day or less of this drug, the MassHealth Drug Utilization Review (DUR) program does not require prior authorization. For doses exceeding this amount, DUR requires a PA request, in part due to the potential for misuse and abuse of this drug, which is a narcotic (Testimony).

The MassHealth representative testified that on March 10, 2022, the appellant's physician, Vincent Paquette, M.D., submitted a PA request to DUR on behalf of the appellant seeking approval for oxycodone HCL IR, 30 mg. tablets, one tablet, three times a day (30-day supply), for management of the appellant's pain caused by lumbago with sciatica (Exh. 3, p. 3). The MassHealth representative noted that Dr. Paquette did not send any of the appellant's medical records with this request. On the same date that the request was received, DUR denied the request by written notice, on the basis that there was insufficient information for DUR to determine medical necessity. The denial notice stated that Dr. Paquette was free to submit another PA request on the appellant's behalf, containing the following: (1) pain specialist evaluation supporting titration to the requested high dose opioid therapy; (2) clinical rationale for not utilizing a long-acting opioid in a member requiring high dose short-acting (IR) opioid therapy for the treatment of chronic pain; and (3) a signed, dated patient-prescriber agreement (Testimony, Exh. 3, p. 9).

The MassHealth representative noted that in preparation for this appeal, DUR sent a letter to the appellant on April 14, 2022, advising her that if her prescriber could supply additional information, DUR might be able to approve the request without a hearing (Testimony, Exh. 3, p. 11). The additional information requested was: (1) copies of the appellant's medical records documenting her treatment plan, including the clinical rationale for the requested high dose and the titration of the requested medication up to the current dose; (2) a copy of a recent pain consult/evaluation from a Board-certified pain specialist physician supporting the requested high dose of oxycodone IR tablets; (3) a copy of a signed, dated patient-prescriber agreement; and (4) a clinical rationale from the prescriber for not utilizing a long-acting opioid agent in a member requiring high dose short-acting opioid therapy for the treatment of chronic pain (*Id.*).

The MassHealth representative stated that DUR received prior to the hearing, from BOH, some medical records of the appellant written by Nicholas Hernandez, M.D., at Brigham and Women's Hospital, [redacted], based on a virtual consult he had with the appellant on January 10, 2022 (Exh. 4). The progress note reflects that the appellant is "status-post total right hip replacement" (*Id*., p. 1). The MassHealth representative pointed out that Dr. Hernandez documented that he discussed with the appellant proceeding with surgery for "hip polyethylene liner and femoral exchange," and further documented:

> [Dr. Hernandez and the appellant] discussed having her see the perioperative pain service prior to surgery given [the appellant's] history of chronic pain medication use.

(Exh. 4, p. 6)

The MassHealth representative stated that none of the other requested documentation, identified above, was received, so DUR stands by its denial of the instant PA request (Testimony).

The MassHealth representative added that extended-release opioids are generally used to address chronic pain, such as the appellant's; immediate-release opioids (such as the requested medication) are generally prescribed to manage acute pain (Testimony).

The appellant, who is under age 65 and lives in the community, testified by telephone that she had a telephonic consult with Devon Flaherty, M.D., a pain specialist physician, as suggested by Dr. Hernandez; she thought she had sent a copy of Dr. Flaherty's progress note to BOH. She stated that she has signed a patient-prescriber agreement with Dr. Paquette, her primary care doctor. She stated that she undergoes urine screens as directed by Dr. Paquette. She stated that she has allergies to morphine, fentanyl, and hydromorphone (Dilaudid). She asserted that she cannot take Tramadol, as it causes her to have seizures (Testimony).

The appellant testified that in 1997, she was involved in a motor vehicle accident, and subsequently had a right hip replacement. This surgery needs to be repeated, but the appellant's surgeon, Dr. Hernandez, recently moved to another city. She has an upcoming appointment with a different surgeon at Brigham and Women's Hospital. In February, 2022, the appellant was involved in another motor vehicle accident, and underwent left wrist surgery for multiple broken bones in March, 2022 (Testimony).

In correspondence to the BOH from the appellant received May 19, 2022 (Exh. 8), the appellant wrote:

> I have a lot of health issues. I'm not out to get certain medications for anything other than my health. I take them as prescribed which (*sic*) I need them. My wrist surgeon. . . I seen (*sic*) on May 9. He offered me a higher dose to take the 30 mg. oxycodone every four hours which would be 90 for 15 days. I could of (*sic*) said yes, but I denied it. . . . I took that dose after my surgery for a month. Now back to my regular amount. I was in a very bad car accident. . . and I had have (*sic*) several broken bones in my wrist. Ribs broken, spinal stenosis. . . .

(*Id*.)

The appellant testified that she also has diagnoses of sciatica and osteoarthritis. She had neck surgery in 2019 following a bad fall. She also underwent gastric bypass surgery in 2015, which failed, resulting in two bowel obstructions and multiple corrective surgeries. In additional correspondence from the appellant received on May 19, 2022, the appellant asserts that she has diagnoses of pancreatitis and sacroiliac joint dysfunction (Exh. 9).

The appellant testified that she was first prescribed oxycodone HCL IR, 15 mg. per day, by Dr. Chang in approximately 2015.[1] Her dosages were increased subsequently by Dr. Burns, and then increased again by Dr. Paquette. She stated that she does not take any oxycodone HCL IR when she drives. She is not currently employed, and is "on disability." Her current dosage of oxycodone HCL IR is one 30 mg. tablet, three times a day. Since MassHealth does not cover this dosage, she pays approximately $80.00 per month for it, out of pocket (Testimony).

At the close of the hearing, the hearing officer agreed to keep the record of this appeal open until July 12, 2022 for the appellant to submit to the hearing officer and to the MassHealth representative a copy of a signed, dated consultation note and/or progress note from Dr. Flaherty, the pain specialist, addressing her use of opioid medications long-term; copies of her medical records documenting the treatment plan for the appellant, including the clinical rationale for the high dose, and titration up, of oxycodone HCL IR 30 mg. to the current dose of 90 mg./day; a copy of a signed, dated patient-prescriber opioid agreement between the appellant and Dr. Paquette; and a documented clinical rationale for not utilizing a long-acting opioid agent in a member requiring high dose, short-acting opioid therapy for the treatment of chronic pain (Exh. 10). Further, the hearing officer gave the MassHealth representative two additional weeks, or until July 26, 2022, to review the appellant's submissions and to respond in writing whether MassHealth would alter its decision to deny the instant PA request (*Id*.).

[1] The appellant testified that Dr. Chang was a family medicine physician and no longer practices medicine.

On or about June 19, 2022, the hearing officer received via e-mail from the appellant a copy of an initial consult note written by Devon Flaherty, M.D., with the Department of Anesthesiology at Brigham and Women's Hospital, based on a thirty-minute virtual visit he had with the appellant on April 14, 2022 (Exh. 11).[2] The consult note reflects that the appellant was "scheduled for revision right hip total arthroplasty" and indicates that the appellant's current dosage of oxycodone HCL IR is "30 mg. TID PRN, which is usually taken in the evening and middle of the night, when her pain is at its worst" (*Id*., p. 2).[3] Dr. Flaherty also documented that the appellant had a motor vehicle accident in February, 2022, resulting in a rib fracture and left distal radius fracture, requiring surgery (*Id*.). Dr. Flaherty documented that the appellant's pain "began several years ago," that her pain is exacerbated by sitting and arising from a sitting position; that the appellant, on the date of the consult, rated her pain as 7 out of 10 in her right hip and low back; that the worst pain the appellant experienced in the week before the consult was 10 out of 10; that the pain is "aching, moderate, soreness and stiff," and that the pain wakes the appellant at night (*Id*.). Dr. Flaherty further documented that the appellant acknowledged to him that IV Fentanyl has worked for her in the past, and that morphine and Dilaudid have caused her intolerable side effects in the past, including hives and nausea (*Id*.).[4]

Dr. Flaherty concluded that following the appellant's planned right hip revision surgery, there is a "likelihood for poorly controlled postoperative pain" (*Id*., p. 5). He documented that during the appellant's planned hospital stay following the upcoming surgery, he "will recommend the anesthesia team consider using multimodal analgesia perioperatively for the purpose of minimizing opioid use. . . ." (*Id*.).

In addition, also on June 19, 2022, the appellant forwarded to the hearing officer by e-mail a copy of a summary from Dr. Chang's office, reflecting that Dr. Chang's physician assistant first prescribed 15 mg. of oxycodone in September, 2013 for the appellant (Exh. 11A). Further, the appellant forwarded a copy of a summary from the office of Geoffrey Burns, M.D. reflecting that as of December, 2014, he prescribed 60 mg. of oxycodone (two 30-mg. tablets) for the appellant by mouth every eight hours for 30 days (Exh. 11B).[5] Dr. Burns continued this dosage of oxycodone for the appellant in March, 2014 (Exh. 11C). In the March, 2014 summary, Dr. Burns documented some of the appellant's diagnoses, including low back pain, chronic pain syndrome, shoulder pain, osteoarthritis of the hip, bursitis, and lumbosacral radiculopathy (*Id*.).

On or about June 21, 2022, the appellant forwarded to the hearing officer by e-mail a copy of a June 21, 2022 letter from a physician assistant at the Brigham and Women's Orthopedics Spine Center at Faulkner Hospital, which states in pertinent part:

> [The appellant] is under the care of Dr. . . .Zampini and [the physician assistant] at Brigham and Women's Faulkner Hospital, Department of Orthopedics.

[2] The hearing officer forwarded a copy of Dr. Flaherty's consult note to the MassHealth representative by e-mail.
[3] TID PRN is three times a day, as needed.
[4] Dr. Flaherty also recommended several non-pharmacologic strategies to the appellant to manage her pain (Exh. 11).
[5] Dr. Burns, in 2013 and 2014, was with the Newton-Wellesley Hospital Pain Management Service (Exh. 11B).

> [The appellant] underwent an anterior cervical decompression and fusion spinal procedure at our office on 12/5/2019. At the time, she was prescribed Oxycontin postoperatively for pain control while she was admitted. Initially, her pain was well-controlled on Oxycontin 10 mg. BID, however, it was soon discontinued due to excessive lethargy and adverse reaction that is considered an allergy.

(Exh. 12)[6]

On or about July 6, 2022, the hearing officer received from the appellant via e-mail a copy of a signed, controlled substance agreement between the appellant and Dr. Paquette, in which the appellant agrees to use a single pharmacy to fill her opioid prescriptions, agrees to take the medication only as instructed, agrees not to sell, share or trade her medication, agrees to undergo random urine or serum toxicology screens as requested, and agrees to refrain from the use of illicit and/or recreational drugs (Exh. 13). This agreement is dated July 5, 2022 (*Id*.).[7]

Also on or about July 6, 2022, the appellant forwarded to the hearing officer via e-mail a copy of a July 5, 2022 letter from Vincent Paquette, M.D., addressed to "whom it may concern," which states in relevant part:

> I am the primary care physician for [the appellant]. She has requested that I give you a brief summary of her need for her chronic pain management. He (*sic*) does have a history of a neck injury secondary to a fall in 2019. She also has a history of low back pain chronically secondary to several motor vehicle accidents treated by orthopedics Dr. Zampini.
>
> She is status-post a right total hip replacement but needs a revision that has been booked for October 5, 2022. . . . This is also a source of chronic pain.
>
> He (*sic*) also has bilateral knee osteoarthritis and sees Orthopedics every three months for frequent injection therapy for pain management as well.
>
> She has had difficulties with multiple drug allergies in the past documented elsewhere. As a result she has had reasonable pain control with her current oxycodone 30 mg. 1 tablet 3 times a day with appropriate PMP search and urine drug screens.

(Exh. 14)[8]

[6] BID is twice a day.
[7] Again, the hearing officer forwarded this document to the MassHealth representative via e-mail.
[8] PMP is an acronym for prescription monitoring program.

Although not requested by the hearing officer, the appellant also sent a partial copy of a recent progress note from her spine physiatrist physician, Zacharia Isaac, M.D., following an office visit on May 23, 2022, stating, among other things, that "[the appellant] is taking oxycodone, but this does provide her with significant relief" (Exh. 15).

The hearing officer forwarded all of the documents he received from the appellant to the MassHealth representative, by e-mail.

On July 26, 2022, the hearing officer received from the MassHealth representative a copy of a response letter to the appellant's record-open submission (Exh. 16).[9] The response letter summarized the content of all the medical records submitted by the appellant following the hearing, and indicated that the consult note from Dr. Flaherty and the signed, dated patient-prescriber opioid agreement were acceptable to MassHealth.

The response letter further states:

> Standard of care and treatment guidelines state that long-acting opioids should be used for severe and continuous pain after patients have received IR opioids daily for at least one week without improvement. For chronic pain, a long-acting agent would be used on a scheduled basis as long-acting opioids provide a steady release of medication, and an IR agent would typically just be utilized for breakthrough pain as needed.

(*Id*., p. 2).

The response letter concludes that a "sufficient clinical rationale as to why [the appellant] cannot utilize a long-acting opioid was not provided" (Exh. 15, p. 3). The response letter asserts that there are various long-acting opioid agents that could be considered to manage the appellant's pain, including buprenorphine transdermal patch, fentanyl transdermal system, levorphanol, methadone, tapentadol extended release, oxymorphone extended release, and tramadol extended release (*Id*.).[10]

Findings of Fact

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

1. The appellant is under age 65 and lives in the community (Testimony).

[9]The MassHealth representative indicated that she had mailed a copy of this response to the appellant.

[10] The response letter indicates that some of these medications would require a PA request to MassHealth, depending on the dosages requested.

2. On March 10, 2022, the appellant's physician, Vincent Paquette, M.D., submitted a PA request to MassHealth DUR on behalf of the appellant seeking approval for oxycodone HCL IR, 30 mg. tablets, one tablet, three times a day (30-day supply), for management of the appellant's pain caused by lumbago with sciatica (Exh. 3, p. 3).

3. On the same date that the request was received, DUR denied the request by written notice, on the basis that there was insufficient information for DUR to determine medical necessity Exh. 1).

4. The appellant filed a timely appeal of this denial with the BOH (Exh, 2).

5. The appellant suffers from chronic pain and has been prescribed oxycodone in various dosages by various physicians since September, 2013 (Testimony, Exh. 11).

6. The appellant was involved in a motor vehicle accident in 1997, and underwent a total right hip replacement (Testimony, Exh. 10, Exh. 13).

7. In March, 2014, Dr. Burns documented some of the appellant's diagnoses, including low back pain, chronic pain syndrome, shoulder pain, osteoarthritis of the hip, bursitis, and lumbosacral radiculopathy (Exh. 11C).

8. The appellant underwent gastric bypass surgery in 2015, which failed, resulting in two bowel obstructions and multiple corrective surgeries (Testimony).

9. The appellant underwent an anterior cervical decompression and fusion spinal procedure at Brigham and Women's Hospital on 12/5/2019 following a fall (Testimony, Exh. 12).

10. Following this surgery, the appellant's pain was well-controlled on Oxycontin 10 mg. BID; however, it was soon discontinued due to excessive lethargy and an adverse reaction (Exh. 12).

11. The appellant has a planned revision right hip total arthroplasty scheduled in October, 2022 (Exh. 13).

12. In February, 2022, the appellant was involved in another motor vehicle accident, resulting in a rib fracture and left distal radius fracture, requiring surgery in March, 2022 (Exh. 11).

13. For doses of 80 mg. per day or less of oxycodone HCL IR, the MassHealth Drug Utilization Review (DUR) program does not require prior authorization (Testimony).

14. For doses of oxycodone HCL IR exceeding 80 mg. per day, DUR requires a PA request, in part due to the potential for misuse and abuse of this drug, which is a narcotic (Testimony).

15. DUR sent a letter to the appellant on April 14, 2022, advising her that if her prescriber could supply additional information, DUR might be able to approve the PA request without a hearing The additional information requested was: (1) copies of the appellant's medical records documenting her treatment plan, including the clinical rationale for the requested high dose and the titration of the requested medication up to the current dose; (2) a copy of a recent pain consult/evaluation from a Board-certified pain specialist physician supporting the requested high dose of oxycodone IR tablets; (3) a copy of a signed, dated patient-prescriber agreement; and (4) a clinical rationale from the prescriber for not utilizing a long-acting opioid agent in a member requiring high dose short-acting opioid therapy for the treatment of chronic pain (Exh. 3, p. 11).

16. The appellant has experienced adverse reactions to other pain medications in the past, including Dilaudid, Tramadol, and morphine (Testimony, Exh. 11).

17. IV Fentanyl has worked well for the appellant's postoperative pain the past (*Id*.).

18. In 2014, the appellant was prescribed up to 180 mg. of oxycodone every day (two 30 mg. tablets every 8 hours) by Dr. Burns (Exh. 11B).

19. Extended-release opioids are generally used to address chronic pain, such as the appellant's, while immediate-release opioids (such as the requested oxycodone HCL IR) are generally prescribed to manage acute pain (Testimony).

20. The appellant has been paying approximately $80.00 per month out of pocket for 90 mg. daily of oxycodone HCL IR (Testimony).

21. During a record-open period following the appeal hearing, the appellant produced a copy of a signed patient-prescriber opioid agreement dated July 5, 2022, and a consultation note from Devon Flaherty, M.D., a pain specialist physician with the Department of Anesthesiology at Brigham and Women's Hospital (Exh. 11, Exh. 13).

22. MassHealth reviewed the appellant's medical records and other documentation submitted by the appellant following the hearing, and concluded that a "sufficient clinical rationale as to why [the appellant] cannot utilize a long-acting opioid was not provided" (Exh. 16, p. 3).

Analysis and Conclusions of Law

Generally, MassHealth will not pay for any services or prescriptions that are not medically necessary (130 CMR 450.204). 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, or 517.007.

130 CMR 450.204(A).

Specifically, regarding pharmaceuticals, MassHealth publishes a Drug List that specifies the drugs that are payable by MassHealth, and these drugs must be "approved by the U.S. Food and Drug Administration ["FDA"] and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8" (130 CMR 406.412(A)(1)).

Oxycodone HCL immediate-release appears on the MassHealth Drug List, with the notation that a prior authorization request is required for dosages greater than 80 mg. per day. MassHealth may approve such a request in its discretion, subject to a showing of medical necessity, pursuant to 130 CMR 406.422(A), which states:

> Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by MassHealth in accordance with 130 CMR 450.303: Prior Authorization. **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 the MassHealth agency for prior authorization for an otherwise noncovered drug.**

(Emphasis added)

In the instant matter, the appellant's physician prescribed oxycodone HCL IR 90 mg./day, for management of the appellant's pain caused by lumbago with sciatica. A PA request was submitted to MassHealth. As it turns out, the appellant has a long history of chronic pain, due to injuries sustained in multiple motor vehicle accidents, osteoarthritis, low back pain, a neck injury, and other conditions. She is scheduled to undergo a right total hip replacement revision surgery this fall.

The evidence shows that the appellant has been prescribed oxycodone since at least 2013, and at one time was prescribed as much as 180 mg./day. She has been prescribed other pain medications, including some narcotics, such as Dilaudid and morphine, but suffered adverse reactions. She also was prescribed Oxycontin postoperatively in 2019, but experienced extreme lethargy. The appellant also suffered seizures when using Tramadol.

The appellant argues that oxycodone HCL IR works well to address her chronic pain. MassHealth, however, points out that standard of care and treatment guidelines reflect that long-acting opioids should be used for severe and continuous pain after patients have received IR opioids daily for at least one week without improvement. For chronic pain, a long-acting agent would be used on a scheduled basis because long-acting opioids provide a steady release of medication, and an IR agent would typically just be utilized for breakthrough pain as needed.

The appellant produced, at MassHealth's request, a copy of a signed, controlled substance agreement between the appellant and her prescriber; however, the agreement was signed on July 5, 2022, after the date of the hearing. Also, the appellant's testimony that fentanyl did not agree with her is at odds with the information contained in the consult note from Dr. Flaherty.

MassHealth, after a thorough review of the appellant's medical records, determined that a sufficient clinical rationale as to why the appellant cannot utilize a long-acting opioid was not provided.

I agree with MassHealth's determination that the appellant has not carried her burden to show why a long-acting, extended-release opioid medication may not be used to address the appellant's pain. It is abundantly clear that the appellant's pain is chronic, and not acute. As such, it may be managed more safely and effectively through the administration of a long-acting, extended-release opioid medication, rather than an immediate-release opioid medication at a dose greater than 80 mg./day.

For these reasons, at this time, the 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.

Paul C. Moore
Hearing Officer
Board of Hearings

cc: MassHealth Drug Utilization Review Program