Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Dismissed in part; Denied in part	**Appeal Number:**	2177448
Decision Date:	12/08/2021	**Hearing Date:**	11/05/2021
Hearing Officer:	Christopher Jones		

Appearance for Appellant:
Pro se

Appearance for MassHealth:
Kristen Danis, Pharm.D.
Phuong Luc, Pharm.D.

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:	Dismissed in part; Denied in part	**Issue:**	Prior Authorization – Pharmaceuticals
Decision Date:	12/08/2021	**Hearing Date:**	11/05/2021
MassHealth's Rep.:	Kristen Danis, Pharm.D.; Phuong Luc, Pharm.D.	**Appellant's Rep.:**	Pro se
Hearing Location:	Quincy Harbor South	**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

On or around October 6, 2021, MassHealth approved the appellant's prior authorization request for "GENOTROPIN MINIQUICK 0.4 MG." Exhibit 2. The appellant filed an appeal on September 28, 2021. Exhibit 3; 130 CMR 610.015(B). Individual MassHealth determinations regarding scope and amount of assistance are grounds for appeal. 130 CMR 610.032.

Action Taken by MassHealth

MassHealth approved the appellant's request for Genotropin 0.4 mg Miniquick injection pens.

Issue

The appeal issue is whether MassHealth was correct, pursuant to 130 CMR 406.413(C)(1), in processing the appellant's prior authorization request.

Summary of Evidence

This appeal involves facts that were largely addressed in Appeal Nos. 2009675 (Jan. 27, 2021) and 1944875 (Dec. 4, 2019). To briefly summarize the relevant facts from Appeal No. 2029675, the appellant has been taking Norditropin for over 10 years. In the past, he was diagnosed with lab-confirmed findings of growth hormone deficiency ("GHD"), though after a decade of treatment his hormone levels remain at the very low end of the normal spectrum. Sometime between in 2013 and

2015, the appellant had a series of appeals with his MassHealth-contracted Managed Care Organization ("MCO"). The result was a confirmation of his GHD diagnosis and a "lifetime" approval for "Norditropin Flexpro 10MG/1.5ML Pen Injcrt." In 2018 or 2019, the appellant was disenrolled from that MCO and MassHealth's Drug Utilization Review ("DUR") unit required a new prior authorization request to continue covering his GHD therapy.[1]

The appellant's prior authorization requests for Norditropin were denied by DUR because the requests were missing clinical documentation needed to support a new diagnosis of GHD and because no clinical rationale was provided for why Norditropin was being requested instead the preferred drug, Genotropin. Appeal No. 2009675 was filed upon a denied request for Norditropin, but while the appeal was pending the appellant's endocrinologist submitted a prior authorization request for Genotropin. The appellant and his endocrinologist agreed there was no clinical rationale for Norditropin over Genotropin, so the request for Norditropin was dismissed. Substantively, the appellant's request for Genotropin was approved based upon two rationales. First, the MassHealth Drug List requirements at that time included (duplicative) language that appeared to indicate that the appellant qualified by hint of having documented complications from GHD.[2]

A second basis for finding the appellant eligible for GHD therapy was that recertifications for GHD therapies required lab results "**within** lab-specific reference range … ." If the appellant's request were considered as a recertification for GHD therapy, as he had been on the medication for over a decade, his lab results would have satisfied the required criteria rather than failed it. Therefore, the appellant's request for Genotropin was approved.

This appeal arises from the appellant's first attempt to have the Genotropin reauthorized. Apparently, MassHealth denied this prior authorization request on the same day it was received, September 23, 2021.[3] MassHealth's representative indicated that this denial was due to the lack of updated labs showing the appellant's current "IGF-1 or IGFBP-3 level within lab-specific reference range … ." On October 6, 2021, MassHealth approved the requested medication through November 6, 2021. On October 27, 2021, the requested medication was approved for a year, through October 27, 2022.[4] In both approvals, the comments section states: "On subsequent requests, please provide

[1] Why the appellant was disenrolled from that MCO continues to be unclear. The specific action giving rise to the disenrollment was not appealed by the appellant.

[2] In the present appeal, MassHealth's representatives that this duplicative requirement for GH deficiency complications was a typographical error. The current prior authorization requirements for Growth Hormones and Increlex (Table 9) now require abnormal lab results **and** GH deficiency complications for initial approvals. See https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=9 (last visited November 23, 2021).

[3] For pharmacy services, MassHealth must act "by telephone or other telecommunication device within 24 hours of the request for prior authorization." 130 CMR 450.303(A)(1). "If a provider submits a request that does not comply with all submission requirements, the MassHealth agency informs the provider … of the relevant requirements, including any applicable program regulations … ." 130 CMR 450.303(A)(2). MassHealth may also authorize "at least a 72-hour supply of a prescription drug" based upon submitted prior authorization requests for pharmacy services. 130 CMR 450.303(A)(1).

[4] Because MassHealth approved the prior authorization request on October 27, 2021, the agency did not prepare a hearing packet for the appeal. What little information there is regarding the receipt and initial denial of the prior authorization request is documented in a printout from the Pharmacy Online Processing System (POPS). See Exhibit 4.

updated clinical documentation (e.g. ***response to therapy and recent/updated IGF-1 or IGFBP-3 laboratory data***.)"

The appellant felt that MassHealth may not deny him based upon his labs, given the fair hearing approval that found his labs were satisfactory to have his GHD therapy covered. MassHealth's representative responded that the approvals for GHD therapies only run for a year at a time, which means he will need to seek prior authorization every year. The recertification criteria differ from the initial certification criteria. For recertification, the labs must show that the appellant's GH levels are **within** a normal range, rather than below it.[5] Furthermore, these labs are simply standard of care to keep track of the appellant's hormone levels to ensure that he is safely and appropriately being treated. The appellant felt that MassHealth was still requesting updated labs too soon, because it had only been eight months from his approval for Genotropin. He argued that MassHealth is treating him differently than it does other members because it is requiring labs be performed more frequently than every 12 months.

MassHealth's representative responded the appellant is being treated the same by being required to submit updated labs every recertification. She acknowledged that this first recertification occurred earlier than 12 months from his approval for Genotropin, but this is due to the appellant's Genotropin being approved through a fair hearing. The appellant's initial request for Genotropin was not reviewed and processed under DUR's typical procedures. Because the hearing officer in Appeal No. 2009675 consolidated the requests for Genotropin and Norditropin, MassHealth backdated the approval for the Genotropin to when the request for Norditropin had been received. The unintended result was that the appellant's prior authorization approval for Genotropin expired before he had received 12 months of Genotropin.[6] She apologized for the difficulty the appellant had in having his GHD therapy approved, and she wanted to be clear MassHealth was moving forward in the same way that it would for anyone seeking recertification.

The appellant then raised an objection to the fact that MassHealth refused to reimburse his out of pocket expenses for purchasing Norditropin pending his last appeal. He testified that, after he was approved for Genotropin, he submitted a letter from his pharmacist and receipts for Norditropin detailing what costs that were actually paid for the Norditropin. The appellant argued that he is entitled to reimbursement under 130 CMR 501.015 for "amounts actually paid for care or services that would have been covered under MassHealth had eligibility been determined correctly, even if these amounts exceed the MassHealth rate." These documents were not offered during this appeal. The appellant's testimony indicated this submission occurred at least six months prior to the hearing. It was pointed out that the appellant never had Norditropin approved because there was never a clinical rationale offered for why Norditropin was being prescribed instead of Genotropin.

The appellant also complained that MassHealth switched his prescription to the "Miniquick" injector from the full-sized pen injector. He explained that he has hand problems that make the smaller injector difficult to use. MassHealth's representative testified that the appellant is welcome

[5] MassHealth's representative also noted that recertification only requires IGF-1 or IGFBP-3 level tests, not a stimulation test.

[6] The timeline may also have been affected by a dosing adjusted.

to have his prescribing physician request whichever version he prefers. MassHealth's representative testified that the delivery mechanism for the medication is not a criterion for prior authorization, MassHealth only reviews for drug and dosage and authorizes whichever mechanism was requested. MassHealth's representative testified that DUR specifically confirmed the Miniquick version with the appellant's prescriber following the last appeal. MassHealth's representative confirmed that the appellant was welcome to have his prescriber resubmit for the full-sized pen. The appellant was incredulous.

Findings of Fact

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

1. On or around January 27, 2021, the appellant's prior authorization request for Genotropin was approved through a fair hearing decision. That decision involved a consolidated appeal regarding the appellant's requests for Norditropin and Genotropin. The request for the Norditropin had been submitted on September 22, 2020; the request for Genotropin had been submitted on November 16, 2020. The prior authorization request for Norditropin was dismissed because the appellant agreed there was no clinical rationale for seeking Norditropin over Genotropin. See Appeal No. 2009675 (Jan. 27, 2021).

2. Following the fair hearing decision, MassHealth authorized the appellant's Genotropin as of September 22, 2020, the date Norditropin had been requested. This date was chosen because the order in the fair hearing decision was unclear as to how to implement the decision. Testimony by MassHealth's representative.

3. On or around September 23, 2021, the appellant submitted a prior authorization request for recertification of Genotropin Miniquick 0.4 MG. Testimony by MassHealth representative; Exhibit 4.

4. MassHealth denied this request because required lab data was not submitted with the recertification request. Testimony by the appellant and MassHealth's representative; Exhibit 4.

5. The appellant filed an appeal on September 28, 2021. Exhibit 3.

6. On October 6, 2021, MassHealth approved the appellant's recertification request for a month. Exhibit 2.

7. On October 27, 2021, MassHealth approved a recertification request for a full year, through October 27, 2022. Exhibit 5.

Analysis and Conclusions of Law

The substance of this appeal was resolved between the parties prior to the hearing, as MassHealth approved the prior authorization request for Genotropin Miniquick 0.5 mg. Therefore, this appeal is DISMISSED pursuant to 130 CMR 610.051(B).

Furthermore, MassHealth behaved reasonably and evenhandedly in processing the appellant's prior authorization request. MassHealth may not approve prescription refills for longer than a year, 130 CMR 406.411(C)(4), and MassHealth must review updated labs reflecting a member's current "IGF-1 or IGFBP-3 level within lab-specific reference range" as part of the recertification criteria for "Adult - GH deficiency or panhypopituitarism (growth hormone agents)." MassHealth Drug List (Available at https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=9 (last visited Nov. 30, 2021)); see also 130 CMR 450.303 130 CMR 406.422 (additional requirements for prior authorization for prescriptions are set out in MassHealth Drug List). The appellant's complaint that labs should not be required more frequently than annually is redundant of the complaint that prior authorization should not be required more frequently.

There is no indication that the appellant has been treated capriciously by receiving less than a year of Genotropin before needing to recertify. The regulations prohibit prescription refills of longer than one-year intervals but are silent as to shorter authorization periods. MassHealth is not required to approve medications on an annual basis. Further, MassHealth's representative presented a reasonable explanation as to why a shorter interval was used in this instance. The agency backdated the appellant's Genotropin prescription to the date of his Norditropin prescription because the two prescriptions were consolidated within one appeal. Many fair hearing decisions order retroactive approvals to ensure that members are held as harmless as possible for delays caused by awaiting fair hearing decisions. Where the hearing officer merged the Genotropin prior authorization request that was not separately appealed into the earlier Norditropin appeal, he created confusion as to how the resulting outcome should be implemented. The decision did not clearly address this confusion, and MassHealth's action in the face of this confusion was a reasonable exercise of its discretion.[7]

Similarly, the appellant's complaints regarding the Miniquick injection mechanism appears to be based in miscommunication rather than malice. From what little evidence there is on this matter, I find MassHealth's testimony credible. MassHealth's understanding of the facts were either firsthand or read from a computer log kept regarding communications. The appellant's testimony was second-hand based upon what he was told by his physician. At this point, any additional evidence is irrelevant. The remedy would be to require MassHealth to provide the appellant's preferential delivery mechanism going forward, but MassHealth's representative confirmed that he could simply have his physician request the change and it would be allowed, as MassHealth has no preference for delivery mechanism, only drug type and dosage. Therefore, to the extent that the appellant seeks an order that he be treated differently by MassHealth's DUR Unit, it is DENIED.

[7] Though not discussed during this hearing, the most recent lab data referenced in Appeal No. 2009675 was from September 8, 2020. The Genotropin prescription from the fair hearing decision was relying upon lab data that was older than one year at the time this prior authorization request was submitted.

The appellant's remaining complaints may identify issues that warrant a fair hearing, but it would be inappropriate to address them in this decision. The appellant raised complaints regarding being disenrolled from an MCO and MassHealth's refusal to reimburse out of pocket expenses. The appellant's fair hearing request identified his dispute with MassHealth to be "a continuation of a Hearing Approved Necessity Drug (-6 months ago)." Typically, a fair hearing must be requested within 30 days of the adverse action for which the member wants a hearing. 130 CMR 610.015(B). During the COVID-19 Federal Public Health Emergency (FPHE), this timeline has been extended to 120 days.[8] The appellant's disenrollment from an MCO occurred at least two years ago, and from his testimony his disagreement regarding reimbursement arose at least six months prior to filing his appeal. Therefore, to the extent that the appellant attempts to have these issues addressed in this hearing, they are DISMISSED as untimely.[9]

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.

Christopher Jones
Hearing Officer
Board of Hearings

cc: MassHealth Representative: UMMS Drug Utilization Review, Commonwealth Medicine, 333 South Street, Shrewsbury, MA 01545

[8] The standard regulation also allows for an extended timeline of 120 days from "the date of request for service when the MassHealth agency fails to act on such request; [or] the date of MassHealth agency action when the MassHealth agency fails to send written notice of the action … ." 130 CMR 610.015(B)(2)(b)-(c).

[9] Even if this appeal could address the appellant's claims regarding reimbursement, there are several reasons why 130 CMR 501.015 would be unavailing at this time. First, the regulation appears directed at members who incur expenses while waiting for MassHealth *coverage* to be approved. 130 CMR 501.015(A). Second, the regulation allows MassHealth to apply prior authorization criteria to any service or prescription for which reimbursement is sought. 130 CMR 515.015(B). The appellant had been repeatedly informed that MassHealth would not cover Norditropin without a clinical rationale for why he could not take Genotropin. See Appeal No. 1944875, p. 4 ("there was still no indication as to whether or not the appellant had tried MassHealth's preferred drug, Genotropin."). Finally, there is no evidence in the record to verify qualifying expenses under 130 CMR 501.015(C).