

**STATE OF MICHIGAN**  
**DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES**  
**Before the Director of Insurance and Financial Services**

**In the matter of:**

██████████  
**Petitioner**

**v**

**File No. 151933-001**

**Health Alliance Plan of Michigan**  
**Respondent**

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**Issued and entered**  
this 29<sup>th</sup> day of February 2016  
by **Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. BACKGROUND**

On January 28, 2016, ██████████, authorized representative of Shawn Dean (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives prescription drug coverage from Health Alliance Plan of Michigan (HAP), a health maintenance organization. The benefits are described in HAP's *Subscriber Contract*. The Director notified HAP of the external review request and asked for the information used to make its final adverse determination. HAP provided its response on February 1, 2016. On February 4, 2016, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization which provided its analysis and recommendation to the Director on February 18, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner is a ██████████ year-old male with low testosterone, a condition also known as hypogonadism. His physician prescribed Androgel. HAP denied coverage.

The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP issued a final adverse determination affirming its denial. The Petitioner now seeks the Director's review of HAP's decision.

### III. ISSUE

Did HAP properly deny prescription drug coverage for Androgel to treat the Petitioner's low testosterone?

### IV. ANALYSIS

#### Respondent's Argument

In its initial denial of coverage, issued on January 13, 2016, HAP wrote:

The FDA has issued safety evaluation regarding the possible risk of cardiovascular events (i.e. stroke, heart attack) in patients taking testosterone products. As a result, the FDA has issued communications that testosterone products are approved ONLY for use in men who lack or have low testosterone levels (hypogonadism) in conjunction with an associated medical condition. Examples include: primary hypogonadism (failure of the testicles to produce testosterone due to specific medical conditions (i.e. Klinefelter syndrome, anorchia, cryptorchidism, leydig cell aplasia), chemotherapy or radiation; and secondary hypogonadism (hypothalamus and pituitary causes) related to Prader-Willi syndrome, Kallmann syndrome, or abnormal LH and FSH production. In addition, according to the FDA, the benefit and safety of testosterone products has not been established for the treatment of low testosterone levels due to aging, even if symptoms seem to be related to low testosterone.

Your plan's coverage Criteria for Testosterone Replacement Therapy (TRT) are in accordance with the FDA label. Testosterone products are covered only for male members who have an associated medical condition (examples above). According to medical information submitted, you do not have an associated medical condition. Therefore, your request for TRT coverage is denied....

In its final adverse determination, HAP stated it had the request for Androgel reviewed by a licensed pharmacist:

After considering all available evidence, previous decisions, and your medication history, we upheld the denial for testosterone gel (Androgel). The use of testosterone replacement products, in men exhibiting symptoms of decreased androgens (i.e. fatigue, decreased libido), is not a covered benefit. None of the FDA-approved testosterone replacement products are approved for use in men with low testosterone levels, who lack an associated medical condition. The benefit and safety of testosterone replacement have not been established for the treatment of low testosterone levels due to aging, even if symptoms seem related to low testosterone. The appeal from [Petitioner's doctor] indicates you have hypogonadism (low testosterone), but no additional information regarding an

underlying medical condition causing low testosterone, resulting in primary or secondary hypogonadism (examples of specific underlying medical conditions were outlined in the original denial), was provided. To satisfy the coverage criteria, the specific underlying medical condition causing the primary or secondary hypogonadism must be documented in the medical records. Therefore, because a specific underlying medical condition for resulting hypogonadism has not been established for primary or secondary hypogonadism, the criteria for the use of testosterone replacement therapy with Androgel have not been satisfied, and the original denial is upheld.

### Petitioner's Argument

In a January 22, 2016, letter filed with the request for an external review, the Petitioner's doctor stated:

I am primary care physician for [Petitioner]. I am appealing to you for approval of his Androgel 1.62 pump.

Of note, he has suffered with hypogonadism, erectile dysfunction and it is documented that he has a low testosterone of 102....He has tried Viagra, Cialis, Stendra and Levitra. These medications have not worked for him. [Petitioner] is also under the care of...his urologist who received an approval for Alprostadil (penile injection). However, he is extremely uncomfortable with the thought of injecting himself and it has affected him emotionally.

### Director's Review

In its adverse determination letters HAP also stated that the Petitioner's low testosterone was due to "aging." However, HAP does not identify any source for concluding that aging is the cause of the Petitioner's condition and the Director can find no reference to such a conclusion in the medical records submitted for this review.

Androgel is listed on HAP's drug formulary and requires HAP's approval before coverage is provided. HAP has asserted that the Petitioner does not meet its criteria for approving the drug. HAP has a medical policy which describes the standards for approval. The specific provision in the medical policy HAP applied to the Petitioner's request is that, according to the U.S. Food and Drug Administration, "testosterone products are approved ONLY for use in men who lack or have low testosterone levels (hypogonadism) in conjunction with an associated medical condition." HAP has asserted that the Petitioner does not have an "associated medical condition" and for that reason is not an appropriate subject for Androgel treatment.

HAP's decision was presented to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician in active practice for more than 10 years who is board certified in urology. The IRO reviewer's report included the following analysis:

[T]his case involves a ■ year-old male who has been diagnosed with chronic neck and back pain. The member has erectile dysfunction that has not responded to PDE5 medications. At issue in this appeal is whether Androgel is medically necessary for treatment of the member's condition.

[C]hronic pain that requires the use of narcotics is a known cause of hypogonadism....PDE5 medications are often ineffective in patients that have untreated hypogonadism....[T]he member meets the Health Plan's criteria for coverage of Androgel and...these criteria are consistent with accepted standards of practice.

Pursuant to the information set forth above and available documentation... Androgel is medically necessary for treatment of the member's condition.

The IRO report contained the following references:

- Clinical Guidelines Panel on Erectile Dysfunction: Summary Report on the Treatment of Organic Erectile Dysfunction:  
<http://www.sciencedirect.com/science/article/pii/S0022534701654193>
- Society for Endocrinology Position Statement on Male Hypogonadism and Ageing:  
[http://www.endocrinology.org/policy/docs/12-10\\_HypogonadismAndAgeing.pdf](http://www.endocrinology.org/policy/docs/12-10_HypogonadismAndAgeing.pdf)
- Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline:  
<http://www.ncbi.nlm.nih.gov/pubmed/20525905>
- Testosterone Replacement Therapy for Male Hypogonadism: Part III. Pharmacologic and Clinical Profiles, Monitoring, Safety Issues, and Potential Future Agents: [http://www.medscape.com/viewarticle/550321\\_1](http://www.medscape.com/viewarticle/550321_1)
- Symptomatic hypogonadism in male survivors of cancer with chronic exposure to opioids:  
<http://onlinelibrary.wiley.com/doi/10.1002/cncr.20028/full>
- Oral Opioids for Chronic Non-cancer Pain: Higher Prevalence of Hypogonadism in Men than in Women:  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2953550/>
- Hypogonadism in men consuming sustained-action oral opioids:  
[http://www.jpain.org/article/S1526-5900\(02\)00032-9/abstract](http://www.jpain.org/article/S1526-5900(02)00032-9/abstract)

According to the IRO report, "chronic pain that requires the use of narcotics is a known cause of hypogonadism....[T]he member meets the Health Plan's criteria for coverage of Androgel." Stated differently, the Petitioner's hypogonadism is caused by his chronic pain which requires the use of narcotics. The chronic pain is the "associated medical condition" that warrants the use of Androgel.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination, the

Director must cite “the principal reason or reasons why the [Director] did not follow the assigned independent review organization’s recommendation.” MCL 550.1911(16)(b). The IRO’s analysis is based on extensive experience, expertise and professional judgment. In addition, the IRO’s recommendation is not contrary to any provision of HAP’s *Subscriber Contract*. MCL 550.1911(15).

The Director, discerning no reason why the IRO’s recommendation should be rejected in the present case, finds that the prescription drug Androgel is medically appropriate, under HAP’s standards, for treatment of the Petitioner’s condition and therefore is a covered benefit under the *Subscriber Contract*.

#### V. ORDER

The Director reverses HAP’s final adverse determination. HAP shall immediately provide coverage for the prescription drug Androgel. See MCL 550.1911(17). HAP shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding the implementation to the Department of Insurance and Financial Services, Health Care Appeals Sections, at this toll free telephone number: (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than sixty days from the date of this order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin

Director

For the Director



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Randall S. Gregg  
Special Deputy Director