

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. 154188-001-SF

University of Michigan, Plan Sponsor
and
MedImpact Healthcare Systems, Plan Administrator
Respondents

Issued and entered
this 21st day of July 2016
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 16, 2016, Dr. ██████████, on behalf of ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services, appealing a claim denial issued by MedImpact Healthcare Systems (MedImpact), the administrator of the Petitioner's prescription drug plan.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's prescription drug plan, sponsored by the University of Michigan, is such a governmental self-funded plan.

The Director notified MedImpact of the request and asked it to provide the information used to make its final adverse determination. MedImpact furnished its response and, on June 28, 2016, the Director accepted the Petitioner's request for review.

This case involves medical issues so the Director assigned it to an independent review organization which provided its analysis and recommendation to the Director on July 11, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 53 years old and has Crohn's disease. Despite medical treatment, she continues to experience severe inflammatory activity principally in the colon with severe chronic abdominal pain. Her gastroenterologist submitted a prior authorization request for the prescription drug Stelara to treat her condition. MedImpact denied the request ruling that Stelara is not medically necessary.

The Petitioner appealed MedImpact's denial of coverage through the plan's internal grievance process. At the conclusion of that process, MedImpact maintained its denial of coverage and informed the Petitioner of its decision in a letter dated June 9, 2016. The Petitioner now seeks the Director's review of MedImpact's denial of coverage.

III. ISSUE

Did MedImpact properly deny prescription drug coverage for Stelara?

IV. ANALYSIS

Respondent's Argument

In its June 9, 2016 final adverse determination, MedImpact wrote:

Your request for a second level review of an adverse benefit determination...was received on 06/06/2016 and sent to Advance Medical Reviews, an External Review Organization (ERO). The ERO has completed its review of your appeal regarding Stelara 90mg/mL which was prescribed by [REDACTED], MD. Your appeal was not approved. A specialist in Internal Medicine, Nephrology at AMR reviewed the case and made the following determination:

Based on the current medical literature, the request for Stelara 90 mg/ml is considered not medically necessary.

This determination is in accordance with your eligibility for coverage and the terms and conditions of your governing plan document's Exclusions & Limitations section in effect at the time services are received.

Petitioner's Argument

In a June 1, 2015 letter to MedImpact, Dr. [REDACTED] wrote:

I am writing on behalf of [Petitioner], a 53 years old female who I have been working with for over a year for management of severe, refractory Crohn's disease. [Petitioner] has previously experienced disease and despite medical maneuvers continues to experience severe inflammatory activity principally in the colon. Her symptoms are severe chronic

abdominal pain due to stricturing disease and substantial reduction in [her] ability to participate in her occupational and social life.

[Petitioner] has used all conventional medical therapies, including corticosteroids, immunomodulators, anti-TNF (humira and remicade) and combination therapy, these have not been able to appreciably improve his condition. She has endured symptoms awaiting response from the agents listed without success. In many situations, we are able to temporize symptoms using corticosteroids. Unfortunately, [t]his disease has not been steroid responsive.

Because her surgical options would be very drastic (a total colectomy and permanent end-ileostomy), we are perusing compassionate approval for ustekinumab (stelara). Ustekinumab (stelara) has completed Phase III clinical trials for treatment of Crohn's disease with an application submitted to the FDA. The efficacy of stelara has been shown in several publications and abstracts at international meetings focused on treating inflammatory bowel disease. There is particular attention to ustekinumab success in the setting of prior anti-TNF primary failure for Crohn's disease. Its alternative mechanism of action (IL-12/23 blockade) and published efficacy supports the potential for therapeutic response where other agents have failed.

* * *

Without offering a potentially effective therapeutic option, specifically ustekinumab, [Petitioner] will have little choice other than major abdominal surgery or continuing to endure incapacitating symptoms. I would propose approval of a 6 month trial of ustekinumab in combination with azathioprine, as a salvage therapy to treat [Petitioner's] Crohn's disease.

Director's Review

To determine whether the prescription drug Stelara is medically necessary to treat the Petitioner's condition, the Director presented this issue to an independent review organization (IRO) for analysis 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, board certified in gastroenterology, who has been in practice for more than 15 years and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

The member has been experiencing abdominal pain along with frequent diarrhea. The member's symptoms were thought to possibly be due to an obstructive process. In May 2016, the member underwent a colonoscopy, which revealed severe colonic strictures that were dilated successfully. It was noted that there was inflammation at the strictured segments. The member also has inflammatory bowel disease-related arthropathy. The

member has tried several therapies without success, including Remicade, Humira, thiopurines and methotrexate, as well as steroids in the form of budesonide and prednisone.

[T]he member has failed conventional treatment with anti-tumor necrosis factor biologics, methotrexate and thiopurines. The member has developed symptomatic stricturing disease and colectomy may be considered. Ustekinumab (Stelara) is a human IgG1k monoclonal antibody that blocks the biologic activity of IL-12 and IL-23 by inhibiting receptors for these cytokines on T cells, natural killer cells and antigen presenting cells. In a phase II trial, 526 patients with moderate to severe Crohn's disease that was resistant to tumor necrosis factor antagonists were randomized to 1, 3 or 6 mg/kg of intravenous ustekinumab or placebo for induction of remission. During the maintenance phase, 145 patients with a response to induction with ustekinumab at 6 weeks were randomized to receive ustekinumab 90 mg subcutaneous or placebo at 8 and 16 weeks. At six weeks, the patients who received 6mg/kg of ustekinumab for induction or remission had significantly higher response rates, as compared to placebo (40% versus 24%). During the maintenance phase, patients with an initial response to ustekinumab had significantly higher rates of response at 69% versus 42% and remission at 42% versus 27% at 22 weeks as compared to placebo. (Sanborn WJ, et al. Ustekinumab induction and maintenance therapy in refractory Crohn's disease. *N Engl J Med.* 2012;367:1519.) Recently, these results were extended in a phase III randomized trial using 2 different ustekinumab doses...[A] statistical significance was demonstrated for the primary and all major secondary endpoints at both intravenous ustekinumab doses. (Sandborn W, et al. A multicenter, double-blind, placebo-controlled phase 3 study of ustekinumab: a human IL-12/30P40 mAb, in moderate-severe Crohn's disease refractory to anti-TNF α ; UNITI-1. *Inflamm Bowel Dis.* 2016 Mar;22(Suppl 1):S1.)

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

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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 in this case is based on extensive experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the prescription drug Stelara is medically necessary for treatment of the

Petitioner's condition and is, therefore, a covered benefit under the terms of the Petitioner's benefit plan.

V. ORDER

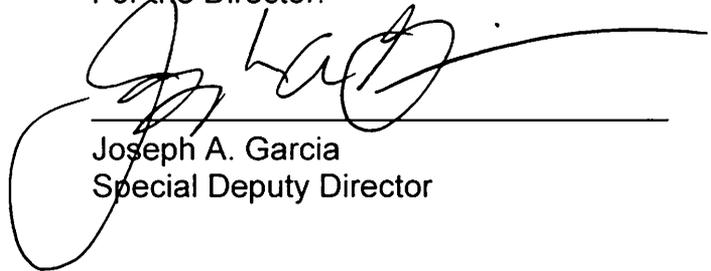
The Director reverses MedImpact's final adverse determination of June 9, 2016. The plan shall immediately provide coverage for the prescription drug Stelara. See MCL 550.1911(17). In addition, MedImpact shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, 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 60 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:



Joseph A. Garcia
Special Deputy Director