

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. 151679-001

Health Alliance Plan of Michigan
Respondent

Issued and entered
this 11th day of February 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 12, 2016, ██████████, authorized representative of ██████████ (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 benefits through a group plan underwritten by Health Alliance Plan of Michigan (HAP), a health maintenance organization. The benefits are defined in HAP's *HMO 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 January 13, 2016. After a preliminary review of the material submitted, the Director accepted the request on January 19, 2016.

To address the medical issues in the case, the Director assigned it to an independent medical review organization which submitted its analysis and recommendation on February 2, 2016.

II. FACTUAL BACKGROUND

The Petitioner is ██████ years old and has leukemia. Her hematologist/oncologist recommended dasatinib (Sprycel) for treatment of her condition. HAP denied coverage.

The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP affirmed its denial in a final adverse determination issued December 11, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did HAP correctly deny coverage for the prescription drug dasatinib?

IV. ANALYSIS

HAP's Argument

In its final adverse determination to the Petitioner, HAP's representative wrote:

After considering all available evidence, previous decisions, and your medication history, we upheld the denial for Sprycel (Dasatinib). Based on the criteria for the use of Sprycel, documentation must show resistance or intolerance to the preferred first line agent, Gleevec (Imatinib), before consideration for coverage of Sprycel, for Chronic Myeloid Leukemia (CML). The physician's [December 9, 2015] appeal letter states that the National Comprehensive Cancer Network (NCCN) Guideline recommends Sprycel for patients with intermediate risk Chronic Myeloid Leukemia (CML) disease, over Imatinib, by stating that "According to NCCN Guidelines, patients should be considered for second a generation tyrosine kinase inhibitor (TKI), like Dasatinib, rather than Imatinib if they have intermediate risk disease per Sokal or Hasford scoring system."

The Guidelines do not make this recommendation and rate all three available TKI's as Category 1 for initial treatment of CML. The Guidelines discuss that preliminary data from DASISION trial¹ suggest that intermediate and high risk patients (as determined by Sokal or Hasford score) may preferentially benefit from Dasatinib, but state that long-term follow up is still needed to determine whether Dasatinib should be implemented as standard first-line therapy in a risk-adapted fashion. Therefore, there is no NCCN recommendation for Sprycel, as recommended therapy over Gleevec for intermediate risk patients, as is cited in the letter.

In addition, final results from the study cited in the appeal letter, DASISION, show no difference in either progression or overall survival between Sprycel or Imatinib groups....HAP's Oncology Pharmacy & Therapeutics Committee comprised of experts from the field, decided that Gleevec is the preferred first line agent for the treatment of CML.

This decision aligns with NCCN guidelines. Per current NCCN guidelines, Gleevec is the recommended first-line agent for CML, based on clinical data that demonstrates efficacy of Gleevec when used in CML, including those patients that have intermediate risk disease. Based on the information provided, the member has not had a trial and failure of Gleevec, nor is there a contraindication to use of Gleevec, to treat CML; therefore, criteria have not been met and Pharmacy Care Management (PCM) recommends upholding the original denial for Sprycel. Please also note that PCM reached out for expert opinion in the field; the response received was in alignment with the above stated rationale for upholding denial.

As part of our investigation, your request was reviewed by one of our licensed Pharmacists, in our Pharmacy Care Management Department, who was not involved in the initial denial.

1. DASISION is an acronym for "Dasatinib versus Imatinib study in treatment-naive CML patients." The study is a randomized phase 3 trial comparing treatment with dasatinib 100 mg QD or imatinib 400 mg QD in patients with newly diagnosed CML-CP. The study is described in *Blood* (Journal of the American Society of Hematology), February 02, 2012; 119 (5) and November 19, 2015; 126(21).

Petitioner's Argument

In a January 12, 2016, letter submitted with the request for an external review, the Petitioner's doctor explained why dasatinib is the most appropriate drug for the Petitioner:

It is our understanding that the denial of this prescription related to a request to prescribe imatinib rather than dasatinib for this indication. Although imatinib is listed as your preferred first line agent, dasatinib also holds a category 1 recommendation for first line therapy in patients with BCR/ABL positive CML in chronic phase, for which this patient qualifies. Additionally, dasatinib is FDA approved in newly diagnosed adults with Philadelphia chromosome-positive chronic myeloid leukemia (CML) in chronic phase. According to the NCCN guidelines, patients should be considered for a second generation TKI, like dasatinib, rather than imatinib if they have intermediate risk disease per Sokal or Hasford scoring system. This is based upon randomized phase III study results indicating superior genetic and molecular responses in this subgroup.

It should be noted that the denial specifically indicated that there was no data indicating enhanced progression free survival (PFS) or overall survival (OS) for dasatinib rather than imatinib in patients with CP-CML. I will note that there is not a single drug approved for CP-CML based upon improvement in either PFS or OS. Even imatinib was approved in 2001 for newly diagnosed CP-CML based upon higher rates of cytogenetic responses compared to interferon. To date, no study has identified a specific tyrosine kinase inhibitor therapy that enhances survival in this disease, and thus, all treatment recommendations are based upon rates of achieving cytogenetic or molecular milestones. Therefore, restricting access to dasatinib based upon a lack of survival data is not supportable. Moreover, in patients with intermediate risk CP-CML, the rates of complete cytogenetic response (CCyR) at 12 month were 78% and 72 % respectively for dasatinib and imatinib. The rates of major molecular responses (MMR) at 12 months were also noteworthy, with 45% of patients treated with dasatinib achieving this milestone, while only 28% of imatinib treated patients meeting this goal.

Director's Review

HAP's decision to deny coverage for dasatinib 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 twelve years who is board certified in hematology and oncology and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

First line treatment with dasatinib (Sprycel) has been prescribed for treatment of the member's condition. Dasatinib is Food and Drug Administration approved for the first line treatment of chronic myeloid leukemia....[D]asatinib is considered category 1 as first line treatment by the NCCN Guidelines....[L]ong-term follow-up data confirmed that dasatinib induces faster and deeper cytogenetic and molecular response in newly diagnosed patients with chronic phase chronic myeloid leukemia with fewer progressions to accelerated or blast phase....[B]oth the NCCN Guidelines and UpToDate considered dasatinib a standard first line therapy for the treatment of CML....[T]he choice of dasatinib over imatinib is often based on a favorable side effect profile as well as the superior responses.

Therefore...the statement in the Health Plan's 12/11/15 adverse determination that indicates that its criteria for the prescription drug Sprycel are in alignment with the NCCN recommendations is not accurate....[T]he NCCN's medical standards for Sprycel are in accordance with current medical standards of care....[C]onsidering the member's condition, she should not be required to try and fail the prescription drug Gleevec before Sprycel. [References omitted.]

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 recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that dasatinib is appropriate under current medical standards for treatment of the Petitioner's condition and is therefore a covered benefit under the benefit contract.

V. ORDER

The Director reverses HAP's final adverse determination of December 11, 2015. HAP shall immediately provide coverage for the dasatinib prescribed for the Petitioner. See section 1911(17) of the Patient's Right to Independent Review Act, 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 its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free 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 Michigan 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:



Randall S. Gregg
Special Deputy Director