

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

v

File No. 120749-001

UnitedHealthcare Insurance Company

Respondent

**Issued and entered
this 26th day of August 2011
by R. Kevin Clinton
Commissioner**

ORDER

I. BACKGROUND

On April 25, 2011, XXXXX authorized representative of her daughter XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.* After reviewing the materials submitted by the Petitioner and her insurer, the Commissioner accepted the case for review.

The case involves a medical issue so the Commissioner assigned the matter to an independent medical review organization, which completed its review and sent its recommendation to the Commissioner on May 12, 2011.

II. FACTUAL BACKGROUND

The Petitioner, who is now XXXXX years old, has a severe inflammatory disease, a condition for which she has been treated since infancy. She has been treated with many drugs which have been effective in controlling her symptoms.

In June 2003, she suffered a severe bout of uveitis, an inflammation of the middle layer of the eye that can cause blindness. In December 2003, Petitioner began treatment with anakinra which has been effective in managing her symptoms. (The drug is also known by its brand name, Kineret.) Without the medication the Petitioner is bedridden, has joint pain and is unable to function normally and causes her to miss school.

In the past, the Petitioner's insurers have provided coverage for this treatment. From April 1 through April 30, 2011 Petitioner received health care benefits under a group policy issued by UnitedHealthcare Insurance Company.

While the UnitedHealthcare policy and related rider includes prescription drug coverage, UnitedHealthcare has denied coverage for Kineret, ruling that it is an experimental or investigational drug for the treatment of Petitioner's condition. Petitioner appealed the denial through UnitedHealthcare's internal grievance process. UnitedHealthcare maintained its denial and issued its final adverse determination dated April 14, 2011.

III. ISSUE

Did UnitedHealthcare correctly deny coverage for the prescription drug anakinra as experimental/investigational under the terms of the prescription drug rider?

IV. ANALYSIS

Petitioner's Argument

In support of continued coverage for anakinra, Petitioner's rheumatologist wrote the following in a letter to UnitedHealthcare dated April 22, 2011:

I am writing to request a further appeal of your recent refusal to cover anakinra injections for [Petitioner] a XXXXX year young woman with NOMID/CINCA who has been taking anakinra since 2003. [Petitioner] has been under our care . . . since 1999, between then and 2003 she was treated with, and failed, prednisone, methotrexate, Enbrel and Remicade. Beginning in 2003 we started her on anakinra and she has done very well; we have weaned her from steroids, her hemoglobin, ESR, CRP are normalize[d] and she attends school and functions as any normal adolescent would.

These medications have been covered without comment by previous insurance companies, but now you have refused coverage for [Petitioner's] medications sighting lack of FDA approval for this indication. First, treatment of many pediatric disorders, especially [a] rheumatologic one requires off label use of medications because the small number of patients and the rarity of the diseases make it prohibitively expensive to conduct large double blind studies with enough patients to obtain useable results. However, there are multiple studies in independent peer reviewed journals supporting the off label use of anakinra to treat NOMID and I am including [a] bibliography of the relevant recent articles.

Respondent's Argument

In its April 14, 2011 final adverse determination, UnitedHealthcare wrote:

Your request for Kineret for the treatment of neonatal onset multisystem inflammatory disease (NOMID) and Uveitis does not meet our criteria for coverage. The decision to deny payment authorization for the drug was based upon indications that we have determined to be proven or the FDA approved indications as listed in the manufacturer's package labeling: Coverage is provided for the treatment of moderate to severe rheumatoid arthritis. Review of literature like PubMed and compendia did not provide articles to support use of drug for this disease. Your prescription drug rider does not include coverage for medications when the medication is used for indications determined by us to be experimental, investigational or unproven.

Commissioner's Review

The prescription drug rider excludes coverage for drugs which are experimental, investigational, or unproven. The drug rider includes this exclusion:

Section 2: Exclusions

* * *

4. Experimental or Investigational or Unproven Services and medications; medications used for experimental indications and/or dosage regimens determined by us to be experimental, investigational or unproven. . . .

In order to answer the question of whether anakinra is experimental, investigational, or unproven for the treatment of Petitioner's condition, the Commissioner obtained the analysis of an independent review organization (IRO) pursuant to section 11(6) of PRIRA, MCL 550.1911(6). The IRO reviewer is a physician who is board certified in physical medicine and rehabilitation and has been in practice for more than 12 years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report includes the following analysis:

[T]he member has used anakinra successfully since 2003. . . . [T]he information provided for review demonstrates that the member has failed multiple other agents, including prednisone, methotrexate, Enbrel and Remicade, before starting anakinra for her severe and sight-threatening uveitis. . . . [T]he member's disease followed a course that is very similar to the course of systemic juvenile rheumatoid arthritis, which is well known to respond to interleukin-1 blockade. . . . [T]he use of anakinra is rational, supported by the literature and safe and effective for treatment of the member's condition. (Neven B, et al. *Arthritis and Rheumatism*. 2010 Jan; 62(1): 258-67. Lovell DJ, et al. *Arthritis Rheum*. 2005 Apr; 52(4):1283-6.)

[The IRO reviewer] determined that Kineret is not experimental /investigational for treatment of the member's condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner 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. The Commissioner can discern no reason why the IRO's recommendation should be rejected in the present case.

V. ORDER

The Commissioner reverses UnitedHealthcare's April 14, 2011, final adverse determination. UnitedHealthcare shall provide coverage for anakinra (Kineret) subject to any applicable deductibles and copayments. UnitedHealthcare shall provide coverage within 60 days from the date of this Order and shall, within seven days of providing coverage, provide the Commissioner with proof it has implemented this Order.

To enforce this Order, Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free (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 Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner