

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
BEFORE THE COMMISSIONER OF FINANCIAL AND INSURANCE REGULATION

XXXXXX

Petitioner

v

File No. 118816-001

Connecticut General Life Insurance Company

Respondent

Issued and entered
this 3rd day of August 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On December 29, 2010, XXXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the information and accepted the request on January 7, 2011.

The case involves medical issues so the matter was assigned to an independent medical review organization, which submitted its analysis on January 21, 2011.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in the Connecticut General Life Insurance Company group policy entitled, *Open Access Plus Medical Benefits* (the certificate).

Petitioner's physician requested authorization from Connecticut General for total ankle arthroplasty surgery utilizing the Salto Talaris anatomic ankle (Salto ankle). Connecticut General denied the request stating that the proposed surgery was experimental/investigational.

Petitioner appealed Connecticut General's denial through its internal grievance process and received Connecticut's final adverse determination dated November 11, 2010.

III. ISSUE

Did Connecticut General properly determine the Petitioner's surgery was experimental/investigational under the terms of the certificate?

IV. ANALYSIS

Petitioner's Argument

The Petitioner states that in 2001 she fell and broke her right ankle requiring pins and a plate to repair the fracture. Since then, the cartilage in the ankle joint has significantly deteriorated, she has lost mobility and has a pronounced limp. She also states movement has become painful and causes pain in her hip and back. She indicates she has tried orthotics and braces but these do not help. She states her condition is worsening. She argues that this surgery offers her the best option for improved quality of life. She believes the surgery is not experimental and is a covered benefit under her coverage.

Her physician, XXXXX, believes that the requested procedure is medically necessary for Petitioner. XXXXX has submitted medical records in support of Petitioner's request.

Respondent's Argument

In denying Petitioner's claim, Respondent cited the "Exclusions, Expenses Not Covered and General Limitations" section of Petitioner's policy, which provides:

Payment for the following is specifically excluded from this plan:

* * *

- for or in connection with experimental, investigational or unproven services.

Experimental, investigational and unproven services are medical, surgical, diagnostic, psychiatric, substance abuse or other health care technologies, supplies, treatments, procedures, drug therapies or devices that are determined by the utilization review Physician to be:

- not demonstrated, through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating or diagnosing the condition or sickness for which its use is proposed;
- not approved by the U.S. Food and Drug Administration (FDA) or other appropriate regulatory agency to be lawfully marketed for the proposed use;

- the subject of review or approval by an Institutional Review Board for the proposed use except as provided in the “Clinical Trials” section of this plan; or
- the subject of an ongoing phase I, II or III clinical trial, except as provided in the “Clinical Trials” section for this plan.

In its final adverse determination, Respondent wrote:

After reviewing the appeal request submitted by XXXXX as well as all supporting documentation, including the benefit plan, the Appeals Committee decided to uphold the original decision to deny authorization for total ankle arthroplasty. The appeal was also reviewed by a board certified Orthopedic Physician. . . .

This decision was based on the following:

- Upon review of all available information, your request for a total ankle arthroplasty cannot be certified. There is insufficient information showing the benefits in large population, multi-center, controlled clinical studies to support the effectiveness of total ankle arthroplasty for any ankle condition. At this present time, it is considered non-standard therapy and falls in the category of experimental, investigational and unproven.

Respondent maintains that its denial of authorization was appropriate under the terms of the certificate.

Commissioner’s Review

The question of whether Petitioner’s surgery was experimental or investigational was presented to an independent medical review organization (IRO) for review as required by section 11(6) of the Patient’s Right to Independent Review Act, MCL 550.1911(6). The assigned IRO physician reviewer is in active clinical practice and is board certified in orthopedic surgery and an adjunct clinical faculty member at a college of medicine. The IRO reviewer’s report included the comments below. (A copy of the complete IRO report is provided to the parties with the Commissioner’s order.)

It is the determination of this reviewer that total arthroplasty is not considered experimental or investigational for this enrollee’s condition.

Total ankle replacement using a Food and Drug Administration (FDA) device in a patient with low physical demand, unimpaired vascular status, without immunosuppression, and with unimpaired hindfoot-ankle alignment, is considered

medically necessary in skeletally mature patients with moderate to severe ankle (tibiotalar) pain that limits daily activity and who have post-traumatic osteoarthritis (as in this case); . . .

The enrollee meets the indications for medical necessity for total ankle arthroplasty as her clinical condition is considered a post-traumatic osteoarthritis.

The proposed procedure is not investigational in nature. This procedure, total ankle arthroplasty, is medically necessary for this enrollee based on the submitted documentation. It is the consensus of experts in the field that total arthroplasty is as safe and effective as ankle fusion for the management of ankle arthritis.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, a recommendation from the IRO 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 Connecticut General's November 11, 2010, final adverse determination. Connecticut General is required to provide coverage for Petitioner's total ankle arthroplasty. Connecticut General shall provide proof of authorization 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, the 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