

Appendix J: Eligible Injuries and Adjustments Criteria

I. Eligible Injury Levels

The following evidence shall be required to establish one of six Eligible Injury Levels. As set forth separately in the outline of terms, to qualify for any of these Eligible Injury Levels, in all cases, a Claimant must establish that (a) the symptoms of his or her alleged Eligible Injury began while such Claimant was taking Olmesartan (other than for Injury Level IV, as set forth below), and (b) the Claimant began taking Olmesartan on, or prior to, May 1, 2015.

A. Injury Level I (SLE I)

An injury shall be classified as Injury Level I upon presenting evidence in a Contemporaneous Medical Record of (1) a diagnosis or pathology records consistent with Sprue-like Enteropathy, as defined in Paragraph 1 below, AND (2) Weight Loss or Hospitalization, as defined in Paragraph 2 below:

1. Diagnosis or Pathology Records:

- a. A pathology report reflecting, concurrent with the use of Olmesartan, a finding of pathologic changes in the lining of the small intestine consistent with villous atrophy including but not limited to blunted, flattened, atrophic, or otherwise compromised villi; or
- b. A diagnosis in a Contemporaneous Medical Record by a treating physician, or expert report for a bellwether case, of Sprue-like Enteropathy (“SLE”), collagenous sprue, or unclassified sprue, or “celiac-like” Enteropathy (“CLE”), or other language in the medical records indicating that (i) the patient was experiencing symptoms consistent with an enteropathic condition, and (ii) that was the reason for discontinuation of Olmesartan; or
- c. A diagnosis in a Medical Record on or prior to December 31, 2016, of another enteropathy condition while on Olmesartan, including but not limited to celiac disease, celiac sprue, gluten sensitivity, malabsorption, microscopic colitis, lymphocytic colitis, or collagenous colitis.

2. Weight Loss or Hospitalization Thresholds:

A Contemporaneous Medical Record reflecting, concurrent with the use of Olmesartan:

- a. weight loss of 5% or more of the Claimant’s body weight attributable to the symptoms of the Claimant’s Eligible Injury; or

- b. hospitalization of three (3) or more days, attributable to the symptoms of the Claimant's Eligible Injury.
- 3. **No Other Etiology:** Notwithstanding Paragraphs A (1) or A (2) above, a Claimant shall not be eligible for this Injury Level if Contemporaneous Medical Records establish that:
 - a. The diarrhea symptoms or pathologic findings resolved completely while the Claimant was using Olmesartan, unless the resolution was due to use of medications (i.e. steroids or anti-diarrheals);
 - b. Claimant stopped using Olmesartan, but, without improvement, (i) continued to experience symptoms of diarrhea more than six (6) months after ceasing use of Olmesartan, or (ii) evidenced blunted, flattened or atrophic villi, more than twelve (12) months after stopping use of Olmesartan;
 - c. Serologic tests indicate the presence of antibodies positive for Celiac Disease (unless there is evidence in the Medical Records that the test result was a false positive or the Claimant's treating physician or a Gastroenterologist submits an affidavit averring that the Claimant does not have Celiac Disease and can tolerate gluten), and the Claimant's symptoms completely resolved or appreciably improved upon being placed on a gluten free diet, while still taking Olmesartan, unless Claimant's symptoms also appreciably improved after discontinuing Olmesartan or the Claimant's physician diagnosed Claimant with one of the diagnoses in I(A)(1)(b); or
 - d. Subsequent to a diagnosis that meets the criteria set out in Paragraph A(1) above, a medical doctor has ruled out such a diagnosis in the Medical Records or it has been determined by a medical doctor, as reflected in the Medical Records, that the enteropathic conditions or pathologic changes to the villi were caused by another medical condition or disease unrelated to Olmesartan use or by another medicine and/or pharmaceutical product, and the Claimant received treatment for that other medical condition that resulted in the symptoms resolving while the Claimant was still taking Olmesartan.

B. Injury Level II (SLE II) Resolution of Symptoms Upon Cessation of Use

An injury shall be classified as Injury Level II upon presenting evidence of (1) a Positive De-Challenge as defined in Paragraph 1 below, AND (2) Weight Loss or Hospitalization, as defined in Paragraph 2 below:

1. Evidence of a Positive De-Challenge. A Positive De-Challenge can be established by evidence in Contemporaneous Medical Records reflecting that:

- a. The Claimant had been experiencing symptoms such as, diarrhea, vomiting, dehydration, or unexplained weight loss (“Symptoms”), concurrent with the use of Olmesartan;
- b. One or more of the Symptoms persisted for more than seven (7) days or “a week,” or language to that effect in the medical records;
- c. The Claimant discontinued Olmesartan; and
- d. The Symptoms improved following discontinuation of use of Olmesartan.

Evidence that the Symptoms improved following discontinuation of use of Olmesartan can be established by (i) Contemporaneous Medical Records reflecting that the Symptoms improved following discontinuation of use of Olmesartan, or (ii) the absence of any references to Symptoms in the Medical Records following discontinuation of use of Olmesartan.

2. Weight Loss/Hospitalization Thresholds

A Contemporaneous Medical Record reflecting, concurrent with the use of Olmesartan:

- a. Weight loss of 5% or more of the Claimant’s body weight attributable to the symptoms of the Claimant’s Eligible Injury; or
- b. Hospitalization of three (3) or more days attributable to the Symptoms of the Claimant’s Eligible Injury.

3. No Other Etiology: Notwithstanding Paragraphs B (1) above, a Claimant shall not be eligible for this Injury Level if Contemporaneous Medical Records establish that:

- a. Claimant evidenced blunted, flattened, or atrophic villi, more than twelve (12) months after stopping use of Olmesartan;
- b. Serologic tests indicate the presence of antibodies positive for Celiac Disease (unless there is evidence in the Medical Records that the test result was a false positive or the Claimant’s treating physician or a Gastroenterologist submits an affidavit averring that the Claimant does not have Celiac Disease and can tolerate gluten),

and the Claimant's symptoms completely resolved or appreciably improved upon being placed on a gluten free diet, while still taking Olmesartan, unless Claimant's symptoms also appreciably improved after discontinuing Olmesartan or the Claimant's physician diagnosed Claimant with one of the diagnoses in I(A)(1)(b); or

- c. A medical doctor has determined that the Symptoms were caused by another medical condition or disease unrelated to Olmesartan use or by another medicine and/or pharmaceutical product, and the Claimant received treatment for that other medical condition that resulted in the symptoms resolving while the Claimant was still taking Olmesartan.

C. Injury Level III: SLE *without* meeting Hospitalization or Weight Loss Thresholds of Injury Levels I or II

An injury shall be classified as Injury Level III if the Claimant meets the requirements of Injury Level I or II but for the Weight Loss or Hospitalization Thresholds for those Injury Levels.

D. Injury Level IV: Aggravation of Symptoms of a Pre-Existing Intestinal Condition While on Olmesartan

1. **Injury Level IV.** An injury shall be classified as Injury Level IV upon presenting evidence in a Contemporaneous Medical Record that:

- a. The Claimant had a pre-existing intestinal condition prior to using Olmesartan causing Symptoms;
- b. The Symptoms persisted for more than seven (7) days or a "week" or language to that effect in the Medical Records while the Claimant was using Olmesartan;
- c. The Symptoms worsened while on Olmesartan; and
- d. The Symptoms improved upon discontinuation of Olmesartan.

Worsening may be shown by unintentional weight loss of more than five pounds associated with Symptoms, or an increase in the number or severity of Symptoms.

2. **No Other Etiologies.** Notwithstanding Paragraph D (1) above, a Claimant shall not be eligible for Injury Level IV if Contemporaneous Medical Records establish that:

- a. The Claimant was suffering from an (a) infectious disease, (b) an inflammatory bowel disease, such as Crohn's, Ulcerative Colitis, radiation enteritis, peptic duodenitis, or diverticulitis, unless such disease pre-existed the use of Olmesartan; or (c) another disease or condition that clearly explains the worsening of the Symptoms; or

- b. The Claimant's medical doctor has determined that Olmesartan was not the cause of the worsening and that another condition, ailment, disease, medicine and/or pharmaceutical product was the cause instead, and the Claimant received treatment for that other medical condition that resulted in the symptoms resolving while the Claimant was still taking Olmesartan.

E. Injury Level V: Persistent Intestinal Symptoms While on Olmesartan

1. **Injury Level V.** An injury that does not meet the criteria for Injury Categories I-IV shall be classified as Injury Level V upon presenting evidence in a Contemporaneous Medical Record of symptoms such as diarrhea, vomiting, nausea, abdominal pain, dehydration, or unexplained weight loss while on Olmesartan, for more than five (5) days during a period of one year.

2. **No Other Etiologies.** Notwithstanding Paragraph E (1) above, a Claimant shall not be eligible for this Injury Level if Contemporaneous Medical Records establish that:

- a) The Claimant's symptoms resolved or appreciably improved upon being placed on a gluten free diet, while still taking Olmesartan, unless Claimant's symptoms also appreciably improved after discontinuing Olmesartan or the Claimant's physician diagnosed Claimant with one of the diagnoses in I(A)(1)(b); or
- b) The Claimant was suffering from an (a) infectious disease, (b) an inflammatory bowel disease, such as Crohn's, Ulcerative Colitis, radiation enteritis, peptic duodenitis, or diverticulitis; or (c) another disease or condition that clearly explains the occurrence of persistent symptoms. In the event that this provision applies to some, but not all, of the days during which the Claimant experienced symptoms, only those days shall be excluded in the count of days toward eligibility.

F. Injury Level VI: Intestinal Symptoms While on Olmesartan

An injury that does not meet the criteria of Injury Categories I-V, shall be classified as Injury Level VI upon presenting evidence in a Contemporaneous Medical Record of symptoms such as diarrhea, vomiting, nausea, abdominal pain, dehydration, or unexplained weight loss, while on Olmesartan. Claimants eligible under this Injury Category shall be entitled to a payment of up to \$10,000 subject to a cap of up to \$4,000,000 for the aggregate of all payments for this Injury Level. In the event that the number of claimants exceeds 400, the payments to each Injury Level 6 claimant shall be reduced *pro rata*. A claimant can satisfy this criteria by submission of an Affidavit, but only if the Claimant submits a certification of no records from the Claimant's treating medical provider(s) confirming that the records have been lost, destroyed, or discarded by the medical provider(s).

II. Base Awards

The base awards shall be as follows:

Level I: 200 points

Level II: 150 points

Level III: 100 points

Level IV: 75 points

Level V: 15 points

Level VI: up to \$10,000 with a cap of \$4,000,000 total for all Injury Level 6 claims (The cap is based on a presumed 400 claims. If there are more than 400 claims, then individual Injury Level 6 awards are reduced pro-rata for all Injury Level 6 claims).

III. Adjustments

Diagnosis and Pathology. For Injury Level I, a Claimant with **BOTH** (a) a diagnosis as defined in Injury Level I (A)(1)(b) or (c) **AND** (b) a pathology report with findings as defined in Injury Level I (A)(1)(a) shall receive an upward points adjustment of [10%].

Hospitalization. For Injury Levels I–V, Claimants who present evidence in Contemporaneous Medical Records documenting visits to a hospital and/or hospitalization (collectively defined as ‘days’ of hospitalization) for treatment of their Eligible Injury (in addition to the number of days required by the applicable Injury Level) shall receive an upward points adjustment. For purposes of adjustments (but not the thresholds set out in Paragraphs A(2) and B(2) above), an ER visit shall count 0.5 hospitalization days if for the purpose of general, rather than acute medical care for the Eligible Injury. The adjustments shall be as follows:

1–3 days of hospitalization: + 20 %

4–7 days of hospitalization: + 40 %

8–14 days of hospitalization: + 80 %

15–30 days of hospitalization: + 150 %

31–60 days of hospitalization: + 250%

61–90 days of hospitalization: + 400 %

91–120 days of hospitalization: + 600 %

>121 days of hospitalization: + 800 %

Weight Loss. For Injury Levels I–V, Claimants who document in Contemporaneous Medical Records unintentional weight loss, concurrent with the use of Olmesartan, of 5% or more of their body weight attributable to the symptoms of the Claimant’s Eligible Injury, shall receive an upward points adjustment as follows:

- 5–10%: + 5 %
- 11–20%: + 10 %
- 21–30%: + 30 %
- 31–40%: + 50 %
- 41–50%: + 70 %
- > 50%: + 100 %

Renal Failure. For Injury Levels I–IV, an upward points adjustment of 10% shall be applied for Claimants who document in Medical Records that they have been diagnosed with renal failure or renal insufficiency which was contemporaneous with their Eligible Injury. A Claimant who is placed on dialysis will get an additional upward points adjustment of 25%.

Long Term Steroidal Use. For Injury Levels I–IV, Claimants who document in Contemporaneous Medical Records and/or Contemporaneous Prescription Records that they were prescribed and used corticosteroid drugs (including but not limited to: budesonide (Entecort) cortisone, hydrocortisone and prednisone) for the treatment of the symptoms of their Eligible Injury for a period of more than forty five (45) days shall receive an upward points adjustment of 10 %.

Adjustment for Usage between June 1, 2009 and July 3, 2013. For Injury Levels I–IV, an upward points adjustment of 10% shall be applied for Claimants who used Olmesartan for a period of time that included the period between June 1, 2009, and July 3, 2013.

Adjustment for Usage after July 3, 2013. For Injury Levels I–IV, an upward points adjustment of 5% shall be applied for Claimants who used Olmesartan for a period of time that included the period between July 3, 2013 and July 3, 2014.