CLAIMS OFFICE
MDL-926 REVISED BREAST IMPLANT SETTLEMENT
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QUESTIONS AND ANSWERS ABOUT GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS) CLAIMS

The questions and answers in this pamphlet address many issues important to claimants making a claim for benefits for General Connective Tissue Symptoms (GCTS).

SECTION 1 GENERAL QUESTIONS

Q1-1 What findings must I have in order to qualify for compensation for GCTS?

A There are two levels of compensation for GCTS (Level A and Level B). Each level has two possible combinations of findings:

Level A:

(1) any two findings from Group I; or
(2) any three non-duplicative findings from Group I or Group II.

Level B:

(1) any finding from Group I plus any four non-duplicative findings from Group II or Group III; or
(2) any two findings from Group II plus one non-duplicative finding from Group III.

Q1-2 What do Group I, Group II and Group III mean?

A The twelve findings for GCTS are divided into three groups. Group 1 includes findings 1-3, Group II includes findings 4-7 and Group III includes findings 8-12. For purposes of compensation, Group I generally carries more weight than Group II or Group III, and Group II carries more weight than Group III.

Q1-3 What is a non-duplicative finding?

A The following are among the duplications on the list of findings:

Rashes (Group I-3 and Group III-8)
Sicca (Group I-2 and Group III-12)
Serological abnormalities (Group II-4 and Group III-9)

Please note that duplicative findings that meet criteria may be credited in either Group, but not in both. The higher Group will be credited whenever possible.

Q1-4 Where can I find the exact criteria for GCTS?

A Read Exhibit E1, specifically: Section 1. General, paragraphs A & B, and Section V. General Connective Tissue Symptoms (GCTS). Read it carefully and completely. Pay particular attention to each word.

Q1-5 Where can I get a copy of Exhibit E1?

A You can call the Claims Office at 1-800-600-0311 or visit our website at www.claimsoffice-926.com.

Q1-6 What should I submit to support my GCTS claim?

A You should submit all underlying medical records that may establish your required findings or laboratory abnormalities, including those establishing the exclusion statements. As such, please send any additional medical records you may have supporting any of your GCTS symptoms to the Claims Office including all underlying office charts, radiology/pathology reports and laboratory test results from any health care professional that provided you with medical care. Examples of health care professionals include the following:

Medical Doctors (M.D.)
Doctors of Osteopathy (D.O.)
Chiropractors
Podiatrists
Dentists
Nurse Practitioners
Optometrists
Occupational Therapists
Physician Assistants
Physical Therapists
Pharmacists

Q1-7 What physician can establish my GCTS findings?

A Many findings require that the physician be board-certified in a particular specialty.

Group I-1 Polyarthritis - any board certified physician

Group 1-2 Keratoconjunctivitis Sicca – any physician

Group 1-3 Immune-mediated skin changes or rashes – either a board-certified Rheumatologist or a board-certified Dermatologist

Group II-4 Positive ANA – any physician

Group II-5 Abnormal cardiopulmonary – depending on the specific finding, it may require a a board-certified Radiologist, a board-certified Cardiologist, a board-certified Internist or a board-certified Pulmonologist

Group II-6 Myositis – any physician, but the muscle biopsy must be interpreted by a pathologist

Group II-7 Peripheral neuropathy or polyneuropathy – a board-certified Neurologist

Group III-8 Other immune-mediated skin changes or rashes – either a board-certified Rheumatologist or board-certified Dermatologist

Group III-9 Serologic abnormalities – any physician

Group III-10 Raynaud's phenomenon – any physician

Group III-11 Myalgias – any physician

Group III-12 Dry mouth – any physician

Q1-8 Can my physician write a letter to summarize my symptoms?

A A letter may be written; however, it is the underlying records that are required to support your findings.

Q1-9 My physician documented all the findings, the exclusion statements and the not pre-existing statements, but he did not sign the letter that stated that my symptoms did not exist before my first implantation. Must I ask him to sign this statement?

A Yes. Your physician must sign all statements that are required to establish a disease claim, including all records establishing your symptoms, the exclusion statements, and the not pre-existing statements.

Q1-10 What is the five (5) year time frame?

A The five (5) year time frame refers to the five years preceding the submission of your claim.

Q1-11 What is the twenty-four (24) month time frame?

A All qualifying findings must have occurred within a single twenty-four (24) month period.

Q1-12 How do I get a phone call from a Claims Officer to discuss my claim?

A Send a completed and signed Request For Assistance Form to the Claims Office.

Q1-13 How do I get a re-review of my claim?

A Send a completed and signed Request For Re-review Form, together with any additional information to be reviewed to the Claims Office.

Q1-14 Where can I get these forms?

A All forms and information concerning the settlement can be obtained by calling 1-800-600-0311. In addition, many of the forms may be obtained from the Claims Office website at www.claimsoffice926.com.

Q1-15 How long do I have to send in additional information about my claim?

A Until the settlement ends on December 15, 2010.

Q1-16 Do I have to correct all the deficiencies in my GCTS letter?

A Not necessarily. It is only necessary to cure the deficiencies for those findings that are needed to meet either Compensation Level A or Compensation Level B. Refer to Exhibit E1 for the requirements for each compensation level.

Q1-17 I have not been able to establish all the findings necessary for Level A or Level B compensation. Can I receive partial compensation for the symptoms I have established?

A No. You must meet all the criteria of a particular compensation level to receive any compensation for your GCTS symptoms.

SECTION 2 EXCLUSIONS AND AFFIRMATIVE STATEMENTS

Q2-1 What is an exclusion?

A An exclusion is a condition that may exist which could disqualify a specific finding.

Q2-2 What is an exclusion statement and who can provide this statement?

A The exclusion statement is a required written statement by the medical doctor who establishes the finding. Please note, merely stating "the exclusions are not present" is not sufficient. The doctor must address all components listed in each specific exclusion.

Q2-3 Where are the exclusions found?

A Within the GCTS criteria, six (6) of the twelve (12) findings require their own specific exclusion. The six findings include:

Group I
Polyarthritis
Keratoconjuctivitis Sicca
Immune-mediated skin changes or rashes (malar rash)

Group II
Myositis
Peripheral neuropathy or polyneuropathy

Group III
Dry mouth

These exclusions are set apart by brackets within the specific part of the finding.

Q2-4 What is meant by the phrase "affirmatively state that the qualifying symptoms did not exist before the date of first implantation?"

A An affirmative statement declares that the finding did not exist before your first breast implantation. Please note that Exhibit E1 requires that these physicians' statements be affirmative. Statements that are not written affirmatively may generate a deficiency.

Q2-5 Who can make the affirmative statement?

A Only the physician making or establishing the finding can make the affirmative statement that the qualifying symptoms did not exist before the date of your first implantation.

Q2-6 How can my current physician provide this affirmation statement without having known me before I had breast implants?

A This statement can be based upon patient history or a review of existing medical records. If it is based upon patient history, it must be consistent with the medical records in the physician's possession. In addition, the Claims Office must receive a copy of the complete patient history taken by the physician.

Q2-7 What is meant by the exclusion of classical rheumatoid arthritis?

A The general overall exclusion for GCTS is classical rheumatoid arthritis. This is in the first paragraph of section V of Exhibit E1. Every claimant seeking compensation for GCTS needs an affirmative statement from a physician stating that the claimant does not have "classical rheumatoid arthritis."

There are several types of rheumatoid arthritis, such as: possible, probable, definite, and classical. A claimant may have a diagnosis of rheumatoid arthritis (possible, probable or definite) and still be eligible for compensation for GCTS. The claimant cannot have "classical" rheumatoid arthritis. If the claimant has classical rheumatoid arthritis, she is not eligible to receive compensation for GCTS.

SECTION 3 GROUP I – POLYARTHRITIS

Q3-1 For the finding of polyarthritis, what are considered to be "different joint groups"?

A The following are considered to be "different joint groups":

Wrists
Elbows
Shoulders
Hips
Knees
Ankles
Joints of the forefoot
Metatarsal phalangeal joints
Interphalangeal joints of the toes
DIP/PIP – distal/proximal interphalangeal joints
MCP – metacarpal phalangeal joints

Q3-2 I have arthritis with tenderness in the joints of my wrists, elbows, and left knee. I have swelling in the left knee and both ankle joints. Do these joints qualify as having polyarthritis?

A No. Exhibit E1 requires that synovial swelling and tenderness are present in at least three of the same joints at the same time.

Q3-3 My doctor is board-certified in Family Practice. Is this an acceptable certification for the finding of polyarthritis?

A Yes. The requirement for Group I-1, polyarthritis, is "a board-certified physician." Exhibit E1 does not require board-certification in any particular specialty, only that the physician be board-certified.

Q3-4 I have one examination for polyarthritis which meets all of the criteria. However, when I returned to my doctor, I had tenderness and swelling in three different joints. Can I ever qualify for polyarthritis if this keeps happening?

A Yes. Exhibit E1 does not require that polyarthritis be observed in the same joints on each examination.

Q3-5 For polyarthritis, provided that the two examinations are more than six weeks apart, do they need to be performed by the same board-certified physician?

A No. You may have physical examinations from two different physicians, as long as each physician is board-certified.

Q3-6 I have osteoarthritis in my right hip. In addition, I have polyarthritis in my hands, wrists and elbows. Because of the exclusion of osteoarthritis, does this mean that I cannot be credited for the symptom of polyarthritis?

A Not necessarily. Polyarthritis may be credited in the presence of osteoarthritis if the joints counted in the diagnosis of polyarthritis are not the joint(s) affected by osteoarthritis.

SECTION 4 GROUP I – KERATOCONJUNCTIVITIS SICCA

Q4-1 I have dry eyes and my doctor is sending me to an optometrist for a Schirmer's test. Shouldn't this test be performed by an ophthalmologist instead?

A Exhibit E1 does not identify who is required to perform the Schirmer's test; however, Exhibit E1 does require that the physician recording a GCTS finding must affirmatively state that the qualifying symptoms did not exist before the date of first implantation and must affirmatively state that the listed exclusions are not present. As a result, an optometrist, who is not a medical doctor (physician), cannot make these statements and cannot satisfy settlement criteria. An ophthalmologist, who is a medical doctor, can provide all documentation needed for this symptom for purposes of the settlement.

Q4-2 Keratoconjunctivitis sicca contains an exclusion for drugs known to cause dry eyes and/or dry mouth. What must my physician say to establish that I am not excluded from this symptom because of my medications?

A The physician documenting your symptom of keratoconjunctivitis sicca must affirmatively state that you are not taking any medications know to cause dry eyes and/or dry mouth.

Q4-3 I wear contact lenses. Does this mean I cannot submit a claim for keratoconjunctivitis sicca?

A No. However, your physician must affirmatively state that your dry eyes are not caused by your contact lenses. To make this statement, your physician may require you to not wear contact lenses for some period of time prior to taking any test to establish your dry eyes.

Q4-4 My physician stated that my Schirmer's test result was less than 8mm in three minutes. Will this test meet settlement criteria?

A No. Your Schirmer's test result must be less than 8mm in five minutes.

Q4-5 My physician stated that I have a positive fluorescein staining of my cornea but not my conjunctiva. Will this meet settlement criteria?

A No. You must have fluorescein staining of both the cornea and the conjunctiva to meet settlement criteria for keratoconjunctivitis sicca.

Q4-6 My physician stated that I have a positive Rose-Bengal and provided the exclusion statements but did not state in my record that I have keratoconjunctivitis sicca. Will my claim be deficient because he did not make that diagnosis?

A No. You do not need a diagnosis of keratoconjunctivitis sicca to meet settlement criteria.

SECTION 5 GROUP I – IMMUNE-MEDIATED SKIN CHANGES OR RASHES

Q5-1 My physician, who is board-eligible, but not board-certified, in Rheumatology, has diagnosed me with discoid lupus and I have had a biopsy showing that. Do I have to see another Rheumatologist or Dermatologist?

A Yes. The discoid lupus must be observed by a board-certified rheumatologist or a board-certified dermatologist to meet settlement criteria even if you already have had a biopsy.

Q5-2 What is a malar rash? Is it any rash on my cheeks?

A The language for the settlement's GCTS finding of malar rash contemplates observation of the classic butterfly rash that is used as a diagnostic criteria by Rheumatologists to diagnose lupus and was taken verbatim from the ARA revised Criteria for Systemic Lupus Erythematous, found in Table 61-11 of Kelley's Textbook of Rheumatology, 4th Ed., p. 1037. The authors of that text call this the "classic butterfly rash" (p. 1020). It is clearly not just any rash or redness that happens to appear on the cheek area. The revised disease criteria requires that this rash is immune-mediated. In addition, your physician must make certain additional statements excluding rosacea and sunburn.

Q5-3 Does my malar rash have to be on both cheeks?

A Yes. The settlement specifies that the malar rash be observed over the "malar eminences" which means both cheeks.

SECTION 6 GROUP II – POSITIVE ANA

Q6-1 Does the laboratory performing the ANA need to report the use of Hep2 as the substrate used?

A No. However, evidence should be provided that the sensitivity of the assay used was in the same range. An ANA reported by immunofluorescence (FANA) would be acceptable; however, an ANA reported using mouse kidney as the substrate is not acceptable.

Q6-2 Concerning the positive ANA finding, does the ANA have to be reported in a titer, or can it be reported in international units (IU/ml)?

A IU/ml is an acceptable method of reporting an ANA; however, the laboratory performing the test must supply their conversion table which converts IU/ml to a titer.

Q6-3 I have two positive ANAs, both in a titer of 1:80; however, the laboratory record does not contain any reference range. Where will these laboratory results be credited?

A Group II-4 requires that all "findings must be outside the performing laboratory's reference ranges." Therefore, provided that the two positive ANAs are at least two months apart, they may be credited in Group III-9, serologic abnormalities, but they would not be credited in Group II-4.

Q6-4 I meet the requirements for Group II-4, positive ANA, with two ANA's of 1:40 (with reference range and Hep2), done two months apart. After my second ANA was positive, I then had the C3 and C4 done, both of which were decreased. Will this finding be credited in Group II?

A No. Exhibit E1 requires that, in order for the ANA to be credited in Group II, one of the positive ANA's must be "accompanied by at least one test showing decreased compliment levels of C3 and C4". In other words, the C3 and C4 must be performed on the same date as one of the ANA tests. However, this finding may be credited in Group III-9, serologic abnormalities.

SECTION 7 GROUP II – ABNORMAL CARDIOPULMONARY SYMPTOMS

Q7-1 I smoked some in college, over twenty years ago. I have recently been diagnosed with interstitial lung disease. Am I barred from this symptom?

A Not necessarily. If you quit smoking many years before your diagnosis of interstitial lung disease, you may still be able to be credited with this symptom. However, your physician should clearly indicate that the interstitial lung disease was not related to your history of smoking. If you were a long-term heavy smoker who quit shortly before receiving the diagnosis, you would not be eligible to be credited with this symptom.

SECTION 8 GROUP II – MYOSITIS OR MYOPATHY

Q8-1 I have an elevated CPK on two separate occasions at least six weeks apart. My EMG records reflect short duration, small, low amplitude polyphasic potential, and fibrillation potentials, but they do not reflect bizarre high-frequency repetitive discharges. Will this meet criteria for myopathy?

A No. Your EMG must also have bizarre high-frequency repetitive discharges to meet the criteria for Group II(a).

SECTION 9 GROUP II – PERIPHERAL NEUROPATHY OR POLYNEUROPATHY

Q9-1 Does the neurologist need to specify how the "loss of sensation" was documented?

A Yes. The neurologist must specify whether the loss of sensation was by pinprick, vibration, touch, or position.

Q9-2 What is meant by symmetrical distal muscle weakness?

A Symmetrical means that the weakness is found in the same distal muscle group on opposite sides of the body, e.g., weakness in the left and right gastrocnemiums (calf) muscles. Distal means a muscle group furthest from the center or from the trunk.

Q9-3 Concerning the exclusion statement for peripheral neuropathy or polyneuropathy, does the "within the last three months" statement apply to infectious disease only?

A Yes.

Q9-4 I have diabetes. Does this make me ineligible to be credited with peripheral neuropathy?

A Yes.

Q9-5 I am a recovering alcoholic and have not had a drink in over ten years. Am I still ineligible to be credited with polyneuropathy?

A Yes.

Q9-6 Does the requirement for "nerve conduction testing abnormality diagnostic of peripheral neuropathy or polyneuropathy recorded from a site that has not undergone neural or muscular biopsy" apply only if I have "loss of tendon reflex"?

A No. For this finding, the word "plus" indicates that, in addition to one of the criteria of (a), (b), (c) or (d), the nerve conduction testing is also required.

Q9-7 My doctor told me I have carpal tunnel syndrome. Is this a creditable finding under peripheral neuropathy or polyneuropathy?

A No. Group II-7 requires more than mere identification of a symptom; rather, it requires an acceptable diagnosis of peripheral neuropathy or polyneuropathy by a board-certified neurologist. Carpal tunnel syndrome, like other entrapment neuropathies, is itself a specific diagnosis that is different than a diagnosis of peripheral neuropathy or polyneuropathy.

SECTION 10 GROUP III – OTHER IMMUNE-MEDIATED SKIN CHANGES OR RASHES

Q10-1 My rheumatologist diagnosed me with livedo reticularis. Must I have a biopsy to prove it?

A No. You are not required to have a biopsy for Group III immune-mediated skin changes or rashes.

Q10-2 I have petechiae in one spot. Is this diffuse petechiae?

A No. Diffuse indicates that the petechiae is not localized to one area.

SECTION 11 GROUP III – SEROLOGIC ABNORMALITIES

Q11-1 My laboratory report for SSA SSB does not indicate that this test was performed by ELISA. My doctor told me the lab always performs this test using the ELISA method. Can my doctor write a letter saying that this was the method used for my SSA SSB?

A No. A written statement from your physician is not acceptable. The laboratory performing the SSA SSB test must provide a written statement regarding the method used to perform the test.

Q11-2 Can the lab result for RF (Rheumatoid Factor) be reported in a "quantitative method", i.e. IU/ml?

A In addition to the criteria in Exhibit E1, an acceptable RF includes a positive finding of Rheumatoid Factor according to the nephelometric method of measuring serum concentrations, where the lab value is above the range considered positive in the lab performing the test (and in no event less than 21 IU/ml).

SECTION 12 GROUP III – RAYNAUD'S PHENOMENON

Q12-1 My medical records clearly show two color changes whenever my doctor sees my Raynaud's. However, he never writes this to be in response to cold. Must the record indicate that, when the doctor sees the color changes, this was in response to cold, or can the "cold-related" be from my history as my records show?

A Exhibit E1 requires that Raynaud's phenomenon be observed by a physician and that he must indicate that he has observed the two color changes to be cold-related.

SECTION 13 GROUP III – MYALGIAS

Q13-1 I have a diagnosis of fibromyalgia and I see a chiropractor at least once a month. Can I use his records which show "tenderness to palpation, in at least three muscles"?

A No. Exhibit E1 requires that tenderness to palpation be performed by a physician. Therefore, we are unable to credit myalgias when the documentation is performed by a chiropractor, physical therapist, nurse practictioner, or physician's assistant.

Q13-2 Does the statement in Group III-11 "each persisting for at least six months" mean that I must have myalgias in the same three muscles for at least six months?

A Yes. Your physician must identify that the tenderness to palpation has persisted in the same three muscles for at least six months.

SECTION 14 GROUP III – DRY MOUTH

Q14-1 My physician stated that my parotid flow rate was less that 0.5 ml but does not state the time frame. Will this test meet settlement criteria?

A No. The physician must state that the parotid flow rate was less than 0.5 ml per five minutes.