

# SF-DCT INFORMATION FOR GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS) CLAIMS

## OPTION 2

**(GCTS Claims are not eligible for  
Disease Option 1)**

# General Connective Tissue Symptoms (GCTS)

- GCTS is a covered condition created in the Revised Settlement Program (RSP) in MDL-926 and included in Disease Payment Option 2 in the Dow Corning bankruptcy settlement.
- To qualify, a claimant must meet any one of the four combinations of eligible findings or symptoms. Claimants who do not qualify for GCTS will be evaluated for Atypical Connective Tissue Disease (ACTD) in Disease Option 1.
- To submit a claim for GCTS, you do not need a diagnosis of GCTS. You do need documentation of the qualifying findings and symptoms. Also, your doctor does not need to state that your eligible findings and symptoms were caused by your breast implants.

# To qualify for GCTS, you must submit the following documents:

To submit a claim for General Connective Tissue Symptoms (GCTS), you must meet ALL of the criteria listed below:

- ❑ 1) A statement that you do not have Classical Rheumatoid Arthritis (known as the CRA exclusion statement, see page 4); **and**
- ❑ 2) All medical records that document the combination of findings or symptoms for GCTS (see pages 5, 86, and 87); **and**
- ❑ 3) If one of your eligible symptoms is either Polyarthritis, Keratoconjunctivitis Sicca, Immune mediated Skin Change-Malar Rash, Myositis -CPK, Peripheral Neuropathy or Polyneuropathy, or Dry Mouth, you must submit a statement from the doctor who documented this symptom excluding certain drugs or conditions as the cause of the symptom (see pages 17, 18, 19, 29, 35, 42, 60, 65, and 68); **and**
- ❑ 4) All your qualifying symptoms must have occurred within a 24 month period (see pages 89 and 92); **and**
- ❑ 5) You must submit your claim to the Settlement Facility within 5 years from the date that your qualifying symptoms were documented. (NOTE: The time frame from May 15, 1995 to May 31, 2004 is tolled for purposes of submitting a claim because Dow Corning was in bankruptcy during this time) (see pages 90 and 91); **and**
- ❑ 6) You must submit a statement from the physician that documents the qualifying finding or symptom stating that you did not have the qualifying finding or symptom before you received your first breast implant (see page 93).

# 1. Statement from your physician that you do not have Classical Rheumatoid Arthritis

You must submit a signed statement from one of your physicians that you do not have Classical Rheumatoid Arthritis (CRA). If you have CRA, you are not eligible for compensation based on GCTS. You may still be eligible for other conditions in the Plan, such as ACTD.

What is Classical Rheumatoid Arthritis? In 1958, a committee of the American Rheumatism Association (ARA) formulated diagnostic criteria for rheumatoid arthritis in an effort to provide guidelines for organized studies of this disease. **These criteria categorized Rheumatoid Arthritis into 4 types: possible, probable, definite, and classical.**

A Claimant can still have possible, probable or definite Rheumatoid Arthritis and still qualify for GCTS. A Claimant who has been diagnosed with Classical Rheumatoid Arthritis will not be eligible for compensation based on GCTS.

If the medical records reflect 7 of the 11 symptoms of Classical Rheumatoid Arthritis, but the file does not reflect a diagnosis of CRA, the claim will be reviewed with the Claims Administrator.

## 2. All medical records that document the combination of findings or symptoms to qualify for GCTS

Only those records that document qualifying findings and symptoms need to be submitted. This includes:

1. All office records from each of the doctors that documented the qualifying findings and symptoms; **and**
2. All lab reports that establish the qualifying findings or symptoms; **and**
3. All reports from x-rays, CT scans, skin biopsies or other tests that establish qualifying findings or symptoms.

The SF-DCT cannot credit the findings and symptoms based solely on a letter from a treating physician. You must submit the underlying medical records and test results.

# What are the eligible findings and symptoms for GCTS?

To qualify for GCTS, your medical records must document a certain number of non-duplicative findings and symptoms. The findings and symptoms are divided into three groups:

Group 1 - Polyarthrititis, Keratoconjunctivitis Sicca, and Immune-mediated Skin Changes or Rashes

Group 2 - Positive ANA, Abnormal Cardiopulmonary Symptoms, Myositis or Myopathy, and Peripheral Neuropathy or Polyneuropathy

Group 3 - Other Immune-mediated Skin Changes or Rashes, Serologic Abnormalities, Raynaud's Phenomenon, Myalgias and Dry Mouth

# How to qualify for GCTS:

To qualify for GCTS, you must meet **ONE** of the following combinations of findings:

For compensation at Level A:

- Any two (2) findings from Group 1 (see pages 9 -48); **or**
- Any three (3) non-duplicative findings from Group 1 or Group 2 (see pages 9 - 69).

For compensation at Level B:

- One (1) finding from Group 1 **PLUS** any four (4) non-duplicative findings from Group 2 or Group 3 (see pages 9 - 85); **or**
- Two (2) findings from Group 2 **PLUS** one (1) non-duplicative finding from Group 3 (see pages 49 - 85).

# Duplicative findings

Certain findings are included in more than one Group in GCTS, these are called duplicative findings.

For example: In Group 1-Keratoconjunctivitis Sicca, the symptoms listed are dry eyes and dry mouth. In Group 3, the symptom is dry mouth. If you receive credit for dry eyes under Keratoconjunctivitis Sicca, then you cannot receive credit for dry mouth in Group 3.

Duplicative findings are:

- √ Immune-mediated Skin Changes or Rashes in Group 1 and Group 3
- √ Keratoconjunctivitis Sicca in Group 1 and Group 3
- √ Serological abnormalities in Group 2 and Group 3

**You cannot use the same qualifying finding or symptom in different groups to qualify for GCTS.**



# Group 1 – Acceptable Proof of Polyarthritiis

To meet the Plan's definition of **Polyarthritiis**, you must meet **ALL** of the following criteria:

1. You must be examined by a board certified physician on at least two different occasions (see page 10); **and**
2. The two examinations must be at least 6 weeks apart (see page 11); **and**
3. Each examination must show synovial swelling and tenderness at the same time (see pages 12 and 13); **and**
4. The swelling and tenderness must be present in three or more joints in at least two different joint groups (see pages 14, 15, and 16); **and**
5. The board certified physician who performs the examinations must make the following statements:
  - a. You do not have Osteoarthritis in the joints in which Polyarthritiis is found (see page 17, 18, and 19); **and**
  - b. You did not have Polyarthritiis before you received your first breast implant (see page 9, 21, and 22); **and**

## Group 1 – Polyarthrititis – Acceptable Board Certified Physician

For Polyarthrititis, the physician performing each examination must be board certified in his or her specialty by the American Board of Medical Specialties (ABMS) or a Doctor of Osteopathy certified by the American Osteopathic Board (AOB)

The Plan does not specify a particular specialty for Polyarthrititis; however, the SF-DCT will only accept physicians who, in the normal scope of their practice, diagnose or treat patients with Polyarthrititis. For example, a board certified ophthalmologist would not be an acceptable board certified physician to record the symptom of Polyarthrititis.

## **Group 1 – Polyarthrititis – Acceptable proof of “persisting for six weeks”**

“Persisting for six weeks” means that the second examination that meets the criteria for Polyarthrititis must be at least 6 weeks after the first examination.

## Group 1 – Polyarthrititis – Acceptable proof of “swelling” in a joint

The following are acceptable terms to describe “swelling” in a joint:

- √ swelling
- √ thickening
- √ fluid
- √ synovial swelling
- √ bogginess
- √ doughy
- √ synovitis
- √ effusion

## Group 1 – Polyarthrititis – Acceptable proof of “tenderness” in a joint

The following are acceptable terms to describe “tenderness” in a joint:

- √ tenderness
- √ sensitivity to pain upon pressure applied to the joint
- √ pain
- √ pain/tenderness on motion (ROM)

## Group 1 – Polyarthrititis – Acceptable proof of swelling and tenderness in three joints of two different joint groups

To credit Polyarthrititis, the swelling and tenderness must be present in three or more joints in at least two different joint groups.

The joints and joint groups found on the second examination do not need to be the same joints or joint groups that were found on the first examination.

## Group 1 – Polyarthrititis – Acceptable proof of “different joints and joint groups”

The following is a list of the joints and joint groups for purposes of Polyarthrititis:

1. Distal Interphalangeal (DIPs) and Proximal Interphalangeal Joints (PIPs) – first two rows of finger joints (count as one joint group)
2. Metacarpal joints (MCPs) – the knuckle joints that connect the fingers to the hand
3. Wrists (the carpal joints that connect the hand to the forearm) and CMC (the thumb joint)
4. Elbows (joints that connect the forearm to the upper arm)
5. Shoulders (joints that connect the arms to the body)
6. Interphalangeal Joints (IPs) (the first joints of the toes)

[continued on next page](#)

## Group 1 – Polyarthrititis – Acceptable proof of “different joints and joint groups”

continued from prior page:

7. Metatarsal Phalangeal Joints (MTPs) (the joints that connect the toes to the forefoot)
8. Sesamoid Bones (the joints of the big toe and forefoot)
9. Ankle joints (joints that connect the foot to the lower leg)
10. Knees (joints that connect the lower leg to the thigh bone)
11. Hips (joints that connect the legs to the body)
12. Sacroiliac Joint (there are 2 sacroiliac joints located on either side of the lower spine and help make up the rear part of the pelvic girdle and sit between the sacrum and the ilia)



## Group 1 – Polyarthrititis – Exclusion Statement for Osteoarthritis

To credit Polyarthrititis, the board certified physician must provide a written statement that you do not have **Osteoarthritis** (the Exclusion Statement). This is a type of arthritis that is caused by the breakdown and eventual loss of the cartilage of one or more joints due to age, obesity and/or excessive wear and tear of the joint.

Synonyms for Osteoarthritis include: degenerative arthritis, degenerative joint disease (DJD), and hypertrophic arthritis, such as Heberden and Bouchard nodes.

If the above synonyms are used to describe a joint, you will not receive credit for Polyarthrititis in those joint areas.

## Group 1 – Polyarthrititis – Exclusion Statement for Osteoarthritis

If you have Osteoarthritis, the SF-DCT can credit you for Polyarthrititis if the joints or joint groups affected by Osteoarthritis are not the same as the joints or joint groups credited for Polyarthrititis.

For example, if you have an x-ray showing Osteoarthritis in both knees and physical exam shows swelling and tenderness in the knees, ankles, PIP joints and MTP joints, then the SF-DCT will not credit the joint group of knees for Polyarthrititis.

We can credit swelling and tenderness in the ankles, PIP and MTP joints. However, the physician who records the examination must provide a statement that Osteoarthritis was not found in the ankle, PIP and MTP joints.

## Group 1 – Polyarthrititis – Acceptable proof of an Exclusion Statement for Osteoarthritis

Acceptable ways that a board certified physician may provide an Exclusion Statement for Osteoarthritis:

- ✓ “Osteoarthritis is not present in the observed joints”
- ✓ “These joints do not show osteoarthritic changes”

# Group 1 – Polyarthritits – Unacceptable proof

**Common reasons why claimants receive a deficiency for the symptom of polyarthritits:**

**Swelling:**

The medical records refer to swelling of the hands and feet. This description is too general and must be distinguished from edema vs. actual joint swelling.

**Tenderness:**

The physician states pain on range of motion and it is clear (s)he is referring to the muscles surrounding the joint and not the actual joint.

Tenderness: A description that only notes stiffness in the joint.

**Swelling and tenderness:**

The physician uses the words “swelling and tenderness” differently in the medical records. For example, the physician states (s)he found swelling and tenderness in the knees and synovitis of the right elbow. The SF-DCT will credit swelling and tenderness in the knees but the right elbow would only be credited for swelling because the physician described tenderness separately and differently for the knee vs. the elbow.

# Group 1 – Unacceptable Proof for Polyarthriti

## Common reasons why claimants receive a deficiency for the symptom of Polyarthriti (continued from previous page):

### Swelling and tenderness:

A diagnosis or description of bursitis alone is not sufficient to describe that swelling and tenderness was found in a joint.

### Joints/Joint groups:

Less than 3 joints and/or less than 2 joint groups reflect swelling and tenderness.

### Pre-existing:

The medical records reflect a diagnosis of Polyarthriti before the first breast implants. Any joints with swelling and tenderness that existed before the first breast implants will not be credited.

### Certification of Physician:

Physician who recorded the symptom of Polyarthriti is not board certified in his specialty.

# Group 1 – Unacceptable Proof for Polyarthritiis

**Common reasons why claimants receive a deficiency for the symptom of Polyarthritiis (continued from previous page):**

**Required Osteoarthritis Exclusion statement:**

- The Exclusion Statement is not in your file.
- The physician who provided the Osteoarthritis (OA) Exclusion Statement is not the physician who recorded the symptom of Polyarthritiis.

**Required statement that your Polyarthritiis did not exist before the date of your first breast implant (This is called the Not Pre-existing Statement):**

- The Not Pre-existing Statement is not in your file.
- The physician who provided the statement that the symptom of Polyarthritiis did not exist before your first breast implant is not the one who recorded the physical exam showing Polyarthritiis.

# Group 1 – Acceptable proof of Keratoconjunctivitis Sicca (K-Sicca)

To credit **Group 1 K-Sicca**, you must submit documents showing the subjective complaint of either dry eyes and/or dry mouth **AND** medical records reflecting the results of any **ONE** (1) of the following two tests (Dry Eyes or Dry Mouth):

**1. DRY EYES:**

- Abnormal Schirmer's test (see page 26); **or**
- Positive Rose Bengal staining (see page 27); **or**
- Positive Fluorescein Staining (see page 28).

**OR**

**2. DRY MOUTH:**

- Abnormal biopsy of a minor salivary gland (see pages 33 and 34); **and**

**3. The physician who performs the examinations must make the following two statements:**

- a. You are not taking any drugs known to cause dry eyes and/or dry mouth. If your qualifying finding is Dry Eyes, your physician must also state that the Dry Eyes are not caused by contact lenses (see pages 29 and 35); **and**
- b. You did not have K-Sicca before you received your first breast implant.

# Group 1 – K-Sicca – Acceptable proof of the subjective complaint of Dry Eyes

To credit the requirement of a subjective complaint of dry eyes, there must be a notation or description in the medical records that you complained of dry eyes. It may be documented from a physician's office questionnaire form or checklist.

If an objective finding of dry eyes is documented on examination, the SF-DCT will credit this as the subjective complaint.

For example, if on exam the physician notes "eyes are dry," the SF-DCT will credit the subjective complaint requirement because an objective finding has a higher standard than a subjective complaint.

The complaint of dry eyes and the test results can be from just one eye. You do not need to complain of dryness in both eyes or have abnormal test results for both eyes.

**Note:** If there is no subjective complaint of dry eyes in the file, but the medical records reflect an abnormal test that confirms dry eyes, the file will be reviewed with the Claims Administrator.



## **Group 1 – K-Sicca – Unacceptable proof of the subjective complaint of Dry Eyes**

Common reasons why claimants receive a deficiency regarding the subjective complaint of dry eyes:

The subjective complaint of dry eyes is from a checklist that was prepared by either the claimant or an attorney. It must be a checklist from the doctor.

The medical records have a notation of “sicca” without sufficient information for the SF-DCT to determine if the symptom is dry eyes or dry mouth.

## Group 1 – K-Sicca – Acceptable proof of a Schirmer’s test for Dry Eyes

**Schirmer’s Test** – This test involves placing a thin tear strip (paper) inside the lower eyelid for 5 minutes. The tear strip is then removed and the length of the strip that is wet from tears is measured and compared to a standard. Individuals with dry eyes will have less wetting of the tear strip than normal. For this symptom to be credited by the SF-DCT, the Schirmer’s Test must show a result of less than 8 millimeters of wetting in 5 minutes.

- The time frame must be at least 5 minutes; it may be longer, for example “ten minutes,” but the amount of wetting still must be less than 8mm.
- The test can be performed by any medical doctor but is generally performed by an ophthalmologist. The test results must include the millimeters of wetting and the time frame in minutes.

## Group 1 – K-Sicca – Acceptable proof of a Rose-Bengal staining test

**Rose Bengal Staining** – Rose Bengal is a dye that, when applied to the cornea and conjunctiva of the eye, is taken up by sick epithelial cells. An abnormal result is noted as a “Positive” Rose Bengal test.

- The test can be performed by any medical doctor but is generally performed by an Ophthalmologist. The records must state or show that the staining was performed on both the cornea and conjunctiva of the eye.

This test may be noted as “RB+.” A notation of “positive” or “abnormal” Rose-Bengal staining in one eye is acceptable as long as it is found in both the corneal and conjunctiva areas.

**A negative test will show no stain, meaning that you do not qualify for K-Sicca as a Group 1 finding.**

# Group 1 – K-Sicca – Acceptable proof of a Fluorescein staining test

**Fluorescein Staining** – This test uses orange dye (Fluorescein) and a blue light to detect foreign bodies in the eye. A piece of blotting paper containing the dye is touched to the surface of the eye, and you will be asked to blink. Blinking spreads the dye around and coats the “tear film” covering the surface of the cornea. A blue light is then directed at your eye. Any problems on the surface of the cornea will be stained by the dye and appear green under the blue light. If the test is normal, the dye remains in the tear film on the surface of the eye and does not adhere to the eye itself.

- The test can be performed by any medical doctor but is generally performed by an Ophthalmologist. The records must state or show that the staining was performed on both the cornea and conjunctiva of the eye.
- Fluorescein staining in one eye is acceptable as long as it is found in both the corneal and conjunctiva areas.

**A negative test will show no stain, meaning that you do not qualify for K-Sicca as a Group 1 finding.**

# Group 1 – K-Sicca – Exclusion Statement For Dry Eyes

Along with the medical records and test results, you must submit the following two statements from the physician who recorded the subjective complaint of dry eyes or performed the acceptable eye test:

1. Your dry eyes were not caused by any drugs or medications known to cause dry eyes and your dry eyes were not caused by contact lenses. (This is called the Exclusion Statement).
2. Your dry eyes did not exist before you received your first breast implant. (This is called the Not Pre-existing Statement)

**The Exclusion Statement must be from a medical doctor. Optometrists are not medical doctors, so the Exclusion Statement cannot be from an Optometrist, but can come from the medical doctor who recorded your Subjective complaint of dry eyes.**

# Group 1 – K-Sicca – Unacceptable Proof for Dry Eyes

## Common reasons why claimants receive a deficiency about the symptom of K-Sicca- Dry Eyes:

- Your medical records reflect a Schirmer's test with results that are equal to or greater than 8 millimeters of wetting.
- Your medical records reflect a Schirmer's test without listing the millimeters of wetting or the time frame for the test (minutes).
- There was no subjective complaint of dry eyes found in your records.
- Your medical records reflect that you were diagnosed with K-Sicca or had dry eyes before you received your first breast implant.
- Your medical records did not contain the Exclusion Statement or the physician who provided the statement is not the physician who recorded the symptom of dry eyes.
- Your medical records did not contain the Not Pre-existing Statement or the physician who provided the statement is not the physician who recorded the symptom of dry eyes.

## Group 1 – K-Sicca – Acceptable proof of Dry Mouth

To credit the requirement of a subjective complaint of dry mouth, there must be a notation or description in the medical records that you complained of dry mouth. It may be documented from a physician's office questionnaire form or checklist.

If an objective finding of dry mouth is documented on examination, the SF-DCT will credit this as the subjective complaint. For example, if on exam the physician notes "dry mouth," the SF-DCT will credit the subjective complaint requirement because an objective finding has a higher standard than a subjective complaint.

**Note:** If there is no subjective complaint of dry mouth in the file, but the medical records reflect an abnormal biopsy report that confirms dry mouth, the file will be reviewed with the Claims Administrator.

## **Group 1 – K-Sicca – Unacceptable proof of subjective complaint of Dry Mouth**

Common reasons why claimants receive a deficiency regarding the subjective complaint of dry mouth:

The subjective complaint of dry mouth is from a checklist that was prepared by either the claimant or an attorney. It must be a checklist from the doctor.

The medical records have a notation of “sicca” without sufficient information for the SF-DCT to determine if the symptom is dry eyes or dry mouth.



## Group 1 – K-Sicca - Salivary glands

There are two types of glands that secrete saliva in the oral cavity: major and minor salivary glands.

Major glands are the parotids, submandibular, and sublingual glands. The sublingual glands are classified as both major and minor salivary glands.

Minor salivary glands are numerous in the oral cavity and are named according to their location: lingual, sublingual, palatal, buccal, labial, and glossopharyngeal. (1)

To credit the symptom of K-Sicca Dry Mouth, you must document an abnormal biopsy of a minor salivary gland.

(1) Source: Website: [www.Medicinenet.com](http://www.Medicinenet.com)

## Group 1 – K-Sicca – Acceptable proof of an Abnormal Biopsy of a Minor Salivary Gland

A minor salivary gland biopsy is the removal of one of the small glands lying beneath the mucous membrane of the lips.

An abnormal labial (lip) salivary biopsy will show grape like clusters on the inner surface of the lips. **The abnormal biopsy report must show a focus score of two or greater based on the average of at least 4 evaluable lobules.**

A focus is defined as a cluster of 50 or more lymphocytes. Lymphocytes are white cells that the body produces as an immune response.

Salivary glands can become infiltrated with these clusters of lymphocytes causing the salivary gland ducts to be blocked and damaged.

## Group 1 – K-Sicca – Exclusion Statement for Dry Mouth

Along with the medical records and test results, you must submit the following two statements from the physician who recorded the subjective complaint of dry mouth or the physician who performed the biopsy test:

1. Your dry mouth was not caused by any drugs or medications known to cause dry mouth. (This is called the Exclusion Statement).
2. Your dry mouth did not exist before you received your first breast implant. (This is called the Not Pre-existing Statement)

# Group 1 – K-Sicca - Unacceptable proof for Dry Mouth

Common reasons why claimants receive a deficiency about the symptom of K-Sicca- Dry Mouth:

- Your salivary gland biopsy report was normal.
- Your salivary gland biopsy was not evaluated or based on the required 4 lobules.
- Your salivary gland biopsy showed a focus score of less than the required 2.
- There was no subjective complaint of dry mouth found in your records.
- Your medical records reflect that you were diagnosed with K-Sicca or had dry mouth before you received your first breast implant.
- Your file did not contain the Exclusion Statement or the physician who provided the statement is not the physician who recorded the symptom of dry mouth.
- Your medical records did not contain the Not Pre-existing Statement or the physician who provided the statement is not the physician who recorded the symptom of dry mouth.

## K-Sicca in Group 1 vs. Sicca Symptoms in Group 3

If you are credited with the Group 1 symptom of K-Sicca, dry eyes or dry mouth, then you cannot use the Group 3 symptom of Sicca- dry mouth to qualify for GCTS.

These are considered duplicative symptoms and you can only receive credit in one group.

# Group 1 – Immune-mediated Skin Changes or Rashes – Documentation needed

To credit **Immune-mediated Skin Change or Rash**, you must submit medical records and test results documenting **ONE** of the following conditions:

**1. Malar Rash (see pages 39-42)**

The office notes from a board-certified Rheumatologist (BCR) or board-certified Dermatologist (BCD) who observes and documents the rash on examination; **and** the BCR or BCD must state that the Malar Rash is not Rosacea or redness caused by sunburn (This is called the Exclusion statement).

**2. Biopsy-proven Rashes**

The office notes from a board-certified Rheumatologist (BCR) or board-certified Dermatologist (BCD) who observes and documents the rash on examination and the biopsy report that confirms that the observed rash is one of the following:

- Discoid lupus (see page 43); or**
- Subacute Cutaneous lupus (see page 44); or**
- Vasculitic skin rash (see pages 45 and 46)**

**AND**

3. The BCR or BCD, who observed the qualifying rash, must provide the statement that your rash did not exist before your first breast implant.

## Group 1 – Immune-mediated Skin changes or Rashes – Malar Rash

**Malar rash** is a fixed erythema, flat or raised over the malar eminences tending to spare the nasolabial folds (the **nasolabial folds** are the deep folds which run from the side of the nose to the corner of the mouth).

The word ‘tending’ means that the rash may include the nasolabial folds and still meet criteria. Also, Settlement language note eminences (which is referring to the cheekbone). This requires the presence of the rash on both sides of the face, cheek, or cheekbones.

## Group 1 – Immune-mediated Skin Changes or Rashes – Acceptable proof of Malar Rash

The following are acceptable terms and ways to describe a malar rash:

- ✓ malar rash
- ✓ butterfly rash
- ✓ malar rash on both cheeks
- ✓ malar erythema on both cheeks
- ✓ rash on cheeks and bridge of nose
- ✓ rash on malar eminences
- ✓ telangiectasia in a malar distribution with fixed erythema



## Group 1 – Immune-mediated Skin Changes or Rashes – Unacceptable proof of Malar Rash

The following descriptions for Malar Rash are unacceptable:

- × facial erythema
- × malar flush
- × malar blush
- × acne rosacea
- × telangiectasia
- × granulomatous rosacea
- × “lupoid or papular rosacea”
- × “erysipelas”(which is a bacterial infection that presents as a malar rash)
- × “acne vulgaris”(this can present in a malar pattern but it is not immune-mediated and will not qualify for malar rash)

## **Group 1 – Immune-mediated Skin Changes or Rashes – Exclusion Statement for Malar Rash**

If you have a Malar Rash, the board-certified Rheumatologist or board-certified Dermatologist who observed it must provide a statement that the malar rash is not rosacea or redness caused by sunburn. (This is called the Exclusion Statement.)

## Group 1 – Immune-mediated Skin Changes or Rashes – Discoid Lupus

**Discoid lupus** is a chronic inflammatory condition limited to the skin. It presents as atrophic skin lesions that are circumscribed and slightly indurated (hardened). The lesions can be red-purple plaques that manifest scaling, follicular plugs, telangiectasias, atrophy, and/or hyper/hypopigmentation.

The outline of the skin lesions tend to be erythematous, sharp, and irregular. They also tend to be chronic and occur mostly on the face, neck, scalp, and ears and infrequently on the upper torso. Discoid rash may also be described as discoid lesion.

## Group 1 – Immune-mediated Skin Changes or Rashes - Subacute Cutaneous Lupus

**Subacute Cutaneous Lupus** is a rash characterized by symmetric, photosensitive non-scarring dermatitis. Circumscribed atrophic patches with hypopigmentation and hyperpigmentation may be seen. Subacute Cutaneous lesions begin as small erythematous, slightly scaly papules that evolve into either a psoriasiform (papulosquamos) or an annular form (annular means circular or ring-shaped). The annular type often combines to form multiple skin lesions that have certain distinct patterns such as round, ring shaped lesions, or shapes similar to “geographic presentations” or maps. Lesions typically have erythematous edges.

The most frequently affected areas are the shoulders, forearms, neck and upper torso. The face is usually spared.

## Group 1 – Immune-mediated Skin Changes or Rashes – Acceptable proof of Vasculitic Skin Rash

**Vasculitis** (angiitis) is an inflammation of a blood or lymph vessel. A vasculitic rash is red or purple dots on the skin caused when small vessels break and produce tiny areas of bleeding in the tissue. To credit this symptom in the Plan, a biopsy of the involved tissue must be taken and it must confirm that it is a vasculitic rash. There are several different types of vasculitic skin rashes. Any biopsy-proven vasculitis is acceptable.

The following are a few examples of the most commonly seen vasculitic rashes that are all acceptable:

Allergic vasculitis

Livedoid vasculitis

Necrotizing vasculitis

Nodular vasculitis

Segmented hyalizing vasculitis (polyarteritis nodosa)

## Group 1 – Immune-mediated Skin Changes or Rashes – Acceptable proof of Vasculitic Skin Rash

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The following are a few examples of the most commonly seen vasculitic rashes that are all acceptable:

Allergic vasculitis

Livedoid vasculitis

Necrotizing vasculitis

Nodular vasculitis

Segmented hyalizing vasculitis (polyarteritis nodosa)

## Group 1 – Immune-mediated Skin Changes or Rashes - Unacceptable proof

**Common reasons why claimants receive a deficiency about the symptom of Immune-mediated Skin Changes or Rashes:**

- The board certified rheumatologist (BCR) or board certified dermatologist (BCD) did not observe the rash.
- Biopsy report did not confirm an acceptable rash.
- The medical records reflect that the rash existed before your first breast implant.
- The physician did not provide the Exclusion Statement for Malar Rash.
- The physician failed to provide the statement that your qualifying rash did not exist before your first breast implant.

## **Immune-mediated Skin Changes or Rashes in Group 1 vs. Immune-mediated Skin Changes or Rashes in Group 3**

If you are credited with the Group 1 symptom of Immune-mediated Skin Changes or Rashes (any of the rashes), then you cannot use the Group 3 symptom of Other Immune-mediated Skin Changes or Rashes to qualify for GCTS.

These are considered duplicative symptoms and you can only receive credit in one group.



## Group 2 - Positive Anti-nuclear Antibody (ANA)

ANA stands for Antinuclear Antibody and it is a blood test that is used to detect autoimmune diseases. The titer level of the ANA is a measure of the amount of the antibody present.

## Group 2 - Positive ANA

There are 2 ways to credit the symptom of **Positive ANA**:

1. Submit two laboratory reports that show a positive ANA **greater than or equal to 1:40** (using Hep2); **and**
2. The positive ANA tests must be performed on two different dates, separated by at least two months; **and**
3. One of the positive ANA tests must be accompanied by a test showing decreased complement levels of C3 and C4;

**or**

1. Submit two laboratory reports that show a positive ANA **greater than or equal to 1:80** (using Hep2); **and**
2. The positive ANA tests must be performed on two different dates, separated by at least two months;

The physician who orders at least one of the ANA tests that meet criteria must state that you did not have a Positive ANA before you received your first breast implant.

**All findings must be outside of the performing laboratory's reference ranges.**

## Group 2 – Acceptable proof for the symptom of Positive ANA

To credit a Positive ANA in Group 2, the laboratory does not need to specify that it used Hep2 substrate method. If there is no substrate method indicated on the laboratory report, then it will be assumed that the Hep2 method was used.

The words “FANA” on the laboratory report indicates that Hep2 was used as the substrate and can be accepted.

If it is noted that a method other than Hep2 was used, then the ANA will not be accepted.

The laboratory report must state that the result of the Claimant’s ANA test result is abnormal according to the Laboratory Facility where the test was performed.

It is acceptable if the ANA is reported in IU/ml if the conversion table of the laboratory is included with the laboratory report. If the SF-DCT cannot determine if the ANA will meet the criteria for a positive result, then you will have to submit a conversion table from the Laboratory Facility where the ANA was performed.

## Group 2 – Unacceptable proof for the symptom of Positive ANA

It is unacceptable for the physician to give the conversion table. The performing laboratory must provide the conversion table. If a conversion table cannot be provided by the facility and the IU/ml result is clearly outside the performing lab's reference range, the issue will be brought to the Claims Supervisor and/or Administrator for discussion.

## Group 2 – The Not Pre-existing Statement for the symptom of Positive ANA

The physician who orders the test that shows an acceptable Positive ANA must provide a statement that you did not have a Positive ANA before you received your first breast implant (This is called the Not Pre-existing Statement).

If the ANA test has the name of an attorney or attorney group listed on the lab report as the ordering person(s), then you may submit the Exclusion Statement from a treating physician at the time the ANA test was performed.

## **Positive ANA in Group 2 vs. Serological Abnormalities in Group 3**

If you are credited with the Group 2 symptom of Positive ANA, then you cannot use the Group 3 symptom of Serologic Abnormalities (any of the tests) to qualify for GCTS.

These are considered duplicative symptoms and you can only receive credit in one group.

## Group 2 - Abnormal Cardiopulmonary Symptoms

To qualify for **Abnormal Cardiopulmonary Symptoms**, you must submit medical records and test results documenting **ONE** of the following conditions:

1. **Pericarditis**- documented by pericardial friction rub and characteristic echocardiogram findings as reported by a Board-certified radiologist or cardiologist (see page 56); **or**
2. **Pleuritic chest pain**- documented by pleural friction rub on exam and chest x-ray diagnostic of pleural effusion as reported by a Board-certified radiologist (see page 57); **or**
3. **Interstitial lung disease**- in a non-smoker diagnosed by a board-certified internist or board-certified pulmonologist, confirmed by **BOTH** (see page 58):
  - (a) chest x-ray or CT evidence as reported by a board-certified radiologist, **and**
  - (b) pulmonary function testing abnormalities defined as decreased DLCO less than 80 percent of predicted; **and**
4. The physician who documents the qualifying finding (1, 2, or 3 above) must state that your condition did not exist before the date you received your first breast implant.

## Group 2 – Abnormal Cardiopulmonary Symptoms- Acceptable proof for Pericarditis

**Pericarditis** is the inflammation of the lining sac (pericardium) that surrounds the heart. Chest pain is the most common symptom. Other symptoms can include weakness, fever, and chills. To receive credit for Pericarditis, you must document **ALL** of the following:

1. Medical records of a physical examination by a physician that shows a pericardial friction rub; **and**
2. The results of an echocardiogram with a diagnosis of pericarditis; **and**
3. The echocardiogram results must be reported by a **board-certified Radiologist** **or** **board-certified Cardiologist**; **and**
4. The board-certified Radiologist or Cardiologist who reported the results must state that you did not have Pericarditis before you received your first breast implant.



## Group 2 – Abnormal Cardiopulmonary Symptoms- Acceptable proof for Pleuritic Chest Pain

**Pleuritic Chest Pain** is usually caused by the inflammation of the pleura, the linings surrounding the lungs. The type of chest pain is usually described as a stabbing pain in the chest aggravated by breathing, chest tenderness, cough, and shortness of breath. To receive credit for Pleuritic Chest Pain, you must document **ALL** of the following:

1. Medical records of a physical examination by a physician that shows a pleural friction rub; **and**
2. The results of a chest x-ray with a diagnosis of pleural effusion; **and**
3. The chest x-ray results must be reported by a **board-certified Radiologist**; **and**
4. The physician who documented the pleural friction rub or the board certified Radiologist who performed the chest x-ray must state that you did not have Pleuritic Chest Pain before you received your first breast implant.

## Group 2 - Abnormal Cardiopulmonary Symptoms- Interstitial Lung Disease

**Interstitial Lung Disease (ILD)** is a general term that includes a variety of chronic lung disorders. When a person has ILD, the lung is affected in three ways. First, the lung tissue is damaged. Second, the walls of the air sacs in the lung become inflamed. Finally, scarring (or fibrosis) begins in the interstitium (or tissue between the air sacs), and the lung becomes stiff. <sup>(1)</sup>

To receive credit for Interstitial Lung Disease, you must document **ALL** of the following:

1. The chest x-ray or CT scan report that confirms ILD; **and**
2. The chest x-ray or CT scan must be read by a **board-certified Radiologist**; **and**
3. A diagnosis of ILD from a **board-certified Internist** or **board-certified Pulmonologist**; **and**
4. An abnormal pulmonary function test (PFT) report that shows a decreased DLCO of less than 80%; **and**
5. The board-certified Internist, board-certified Pulmonologist, or board-certified Radiologist that documented the condition must state that you did not have ILD before the date you received your first breast implant.

(1) Source: Website: [www.lungusa.org](http://www.lungusa.org)

## Group 2 – Unacceptable proof for Abnormal Cardiopulmonary Symptoms

### Common reasons why claimants receive a deficiency about Abnormal Cardiopulmonary Symptoms:

- There is no pericardial rub documented by a physician.
- The echo report did not reflect pericarditis.
- The echo results was not reported by a board certified radiologist or board certified cardiologist.
- There was no pleural friction rub documented by a physician.
- The chest x-ray that reflects pleural effusion was not reported by a board certified radiologist
- Your records reflect that you are a smoker or quit smoking less than 15 years before the onset of the interstitial lung disease (ILD) condition.
- The diagnosis of ILD was not from a board certified internist or board certified Pulmonologist or the chest x-ray and PFT did not meet criteria.
- The board certified physician failed to provide the statement that your qualifying abnormal cardiopulmonary symptom did not exist before your first breast implant.

## Group 2 - Myositis or Myopathy

**Myositis** is a general term for inflammation of the muscles. **Myopathy** is a disease or condition that affects the skeletal muscles. To receive credit for Myositis or Myopathy, you must submit documentation of **TWO** the following:

1. EMG report showing changes characteristic of myositis: short duration, small, low amplitude polyphasic potential; fibrillation potentials; and bizarre high-frequency repetitive discharges; **and/or**
2. Laboratory tests showing abnormally elevated CPK or aldolase from the muscle (outside of the performing laboratory's reference ranges) on two separate occasions at least six weeks apart. (**and/or**)
3. Report of a muscle biopsy (at a site that has not undergone EMG testing) showing evidence of necrosis of type 1 and 2 muscle fibers, phagocytosis, and an interstitial or perivascular inflammatory response interpreted as characteristic of myositis or myopathy by a pathologist;

**For CPK only:** A statement from the doctor who orders the tests that the abnormal test result above were not caused by injections, trauma, hypothyroidism, prolonged exercise, or drugs known to cause abnormal CPK or Aldolase (This is called the Exclusion Statement)

## Group 2 – Myositis or Myopathy – Acceptable proof of EMG

**EMG** stands for Electromyography. A needle electrode is inserted into the skeletal muscle and measures and records the electrical activity of the muscle at rest and during contraction. It is used to evaluate patients with diffuse or localized muscle weakness.

The EMG must show **all** of the following changes characteristic of myositis:

1. short duration, small, low amplitude; **and**
2. polyphasic potential; **and**
3. fibrillation potentials; **and**
4. bizarre high-frequency repetitive discharges.

## Group 2 – Myositis or Myopathy – Acceptable proof of Abnormal CPK or Aldolase

To credit an Abnormal CPK or Aldolase, you must submit ALL of the following:

1. Two abnormally elevated CPK or Aldolase test results; **and**
2. Both tests must be outside of the performing laboratory's normal reference ranges; **and**
3. The two abnormal tests must be at least six weeks apart.
4. If the level of the initial test is three times the normal value or greater, one test will be sufficient.

**Serum muscle enzymes** are measured by a blood test.

- **CPK (CP, CK)** – (creatine kinase, creatinine phosphokinase). CK or CPK is a blood test that measures creatine phosphokinase, an enzyme found mainly in the heart, brain and skeletal muscle. When the total CPK level is very high, it usually means there has been injury or stress to the heart, the brain, or muscle tissue. For example, when a muscle is damaged, CPK leaks into the bloodstream. Determining which specific form of CPK is high helps doctors determine which exact tissue has been damaged; **or**
- **Aldolase** – Aldolase is present most significantly in skeletal and heart muscle. Damage to skeletal muscle produces high serum levels of aldolase, particularly in the case of progressive muscular dystrophy.

## Group 2 – Myositis or Myopathy – Acceptable proof of a Muscle Biopsy

A **Muscle Biopsy** is the removal of muscle tissue for microscopic examination and chemical analysis. It can be done either by a needle or through surgical removal of several samples from the muscle site. To credit the Muscle Biopsy, you must document **ALL** of the following:

1. Evidence of necrosis of type 1 and 2 muscle fibers; **and**
2. Phagocytosis; **and**
3. Interstitial or perivascular inflammatory response; **and**
4. Interpreted as characteristic of myositis or myopathy by a pathologist; **and**
5. The muscle biopsy must be from a site that has not undergone any EMG testing.

## Group 2 – Unacceptable proof of Myositis or Myopathy

### Common reasons why claimants receive a deficiency for Myositis or Myopathy:

- You have a diagnosis of Myositis or Myopathy before the date of your first breast implant.
- Your medical records have a diagnosis of Myositis or Myopathy but you did not submit the abnormal test result or the test result was not abnormal (for example, the CK or CPK laboratory results are decreased rather than elevated).
- Your physician directly relates your Myositis or Myopathy to another cause or condition.



## Group 2 - Peripheral or Polyneuropathy

**Peripheral neuropathy** is a problem with the nerves that carry information to and from the brain and spinal cord that can cause numbness, weakness, pricking sensations, sensitivity to touch, burning pain, loss of sensation and/or reflexes, and muscle weakness. **Polyneuropathy** is when many nerves are simultaneously affected. To receive credit for Peripheral Neuropathy, you must submit **ALL** of the following:

1. A diagnosis of Peripheral or Polyneuropathy from a board-certified Neurologist; **and**
2. Records and tests results from **ONE** (1) of the following:
  - a. Objective loss of sensation to pinprick, vibration, touch or position; **or**
  - b. Symmetrical distal muscle weakness; **or**
  - c. Tingling and/or burning pain in the extremities ( i.e., hand, arms, foot, leg); **or**
  - d. Loss of tendon reflex (noted as absent, decreased or abnormal); **and**
3. Nerve conduction testing abnormality diagnostic of peripheral neuropathy or polyneuropathy recorded from a site that has not undergone neural or muscular biopsy; **and**
4. A statement from the doctor that states that your condition was not caused by thyroid disease, antineoplastic treatment, alcoholism or other drug dependencies, diabetes, or infectious disease within the last three months preceding the diagnosis; **and**
5. A statement from the doctor that you did not have Peripheral or Polyneuropathy before the date you received your first breast implant.

# Group 2 – Peripheral or Polyneuropathy

## Acceptable proof includes:

1. Objective loss of sensation to pinprick, vibration, touch or position must be found on a physical exam. The physical exam must specify how the “loss of sensation” was documented, for example by “touch” or “vibration” or “position.”
2. Symmetrical distal muscle weakness must be found on a physical exam, and the weakness must be in the same distal muscle group on both sides of the body. For example, weakness in the left and right solis (feet). The muscle weakness can be proven in such ways as strength testing using 0-5 strength measurement (with 5 being normal and less than 5 is acceptable proof) or functional testing such as standing on heels and toes to show distal weakness.
3. A complaint of tingling and/or burning pain in the extremities may be used to confirm this finding. The subjective complaint must be found as a present complaint of symptoms in the office notes of the examination and not just in a recited past history.
4. An observed decrease in tendon reflex must be found on physical exam. A grading scale is sometimes used to enable a comparison of the findings from one reflex to another. A loss of tendon reflex would be indicated by a loss from the Claimant’s baseline. For example: Ankle reflexes measured at “0” would be a loss, if reflex of “1+” were indicated in all other areas to be normal. A knee reflex of “1+” would be a loss, if reflex of 2+ were indicated in all other areas. Also, if on examination, the physician notes evidence of asymmetrical decrease in reflexes; this is acceptable.

## Group 2 – Peripheral or Polyneuroathy - Nerve Conduction Test (NCT)

Acceptable proof of a **Nerve Conduction Test** includes:

1. The nerve conduction test must confirm the diagnosis of peripheral neuropathy or polyneuropathy; **and**
2. The nerve conduction test must be from a site that has not undergone neural or muscular biopsy; **and**
3. The NCT must be from the same site of the complaint of the symptom. For example, if the Claimant has the diagnosis of peripheral neuropathy and the “complaint of tingling” is in the left leg, then the abnormal NCT must be from the left lower extremity.

The nerve conduction test is not required to be performed by the board certified neurologist.

## Group 2 – Unacceptable proof of Peripheral or Polyneuropathy

### Common reasons why claimants receive a deficiency for Peripheral or Polyneuropathy:

1. The records document that the claimant has Carpal Tunnel Syndrome (CTS) or Tarsal Tunnel Syndrome (TTS). CTS or TTS are specific types of compression and entrapment neuropathies and are often a result of a mechanical compromise as in a work related injury.
2. A prior history of alcoholism, drug dependency, or diabetes. If you have a history of any of these conditions, you cannot use the symptom of Peripheral or Polyneuropathy.
3. Your records show that you received treatment with antineoplastic agents (drugs used to treat cancer) or a past history of thyroid disease. The time between the chemotherapy or thyroid disease and when the diagnosis of Peripheral or Polyneuropathy was made will be taken into consideration. For example, a Claimant who had been treated in the past with antineoplastic agents and never had any symptoms of Peripheral Neuropathy (PN) during or after the antineoplastic agents, but now many years later develops PN will not automatically be excluded from qualifying for this Finding.
4. Your records show the presence of an infectious disease within the last three months prior to the diagnosis of Peripheral or Polyneuropathy. This time limitation only applies to infectious disease. Infectious diseases that may cause or impact neuropathies include, but are not limited to Leprosy, Guillian Barre, infectious polyneuritis, infectious mononucleosis, viral hepatitis, acute porphyries and AIDS.

## Group 2 – Unacceptable proof of Peripheral or Polyneuropathy

**Common reasons why claimants receive a deficiency for Peripheral or Polyneuropathy (continued from previous page):**

5. The diagnosis of Peripheral Neuropathy or Polyneuropathy was not from a board certified Neurologist (BCN).
6. The board certified neurologist failed to provide the statement that your peripheral or polyneuropathy did not exist before your first breast implant.
7. Your medical records reflect Peripheral or Polyneuropathy existed before your first breast implant.

## Group 3 - Other Immune-mediated Skin Changes or Rashes

To receive credit for a **Group 3 Immune-mediated Skin Change or Rash**, you must submit **ALL** of the following:

1. Medical records from an examination by a board-certified rheumatologist or board-certified Dermatologist documenting that one of the following rashes was observed:
  - (a) livedo reticularis; **or**
  - (b) lilac (heliotrope), erythematous scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli; **or**
  - (c) Gottron's sign, pink to violaceous scaling areas typically found over the knuckles, elbows, and knees; **or**
  - (d) diffuse petechiae

### **AND**

2. The board-certified Rheumatologist or board-certified Dermatologist must state that the qualifying rash did not exist before the date you received your first breast implant.

## Group 3 – Other Immune-mediated Skin Changes or Rashes

**Livedo reticularis** is a disorder in which blood vessels are constricted, or narrowed. It results in mottled discoloring (reddish blue) on large areas of the legs or arms and most often localized in the lower extremities.

A **lilac or heliotrope rash** is a reddish-purple rash that covers the upper eyelids. It may also show as erythematous or redness of the skin produced by congestion of the capillaries. This rash may be found around the medial malleoli, which is the surface of the ankle joint.

**Groton's Sign** are red, scaly lesions that cover certain joints like the knees and elbows.

**Petechiae** are small (less than 3 millimeters in diameter), flat round red spots under the skin surface caused by bleeding into the skin. The medical records do not have use the word “diffuse” but the office notes must have some documentation that the petechiae is in a scattered pattern and not localized to one area.

## Group 3 – Unacceptable proof for Other Immune-mediated Skin Changes or Rashes

Common reasons why claimants receive a deficiency about the Group 3 symptom of Other Immune-mediated Skin Changes or Rashes:

- The rash is noted in the medical records but it was not found on examination.
- A physician states that the rash is directly related to something other than breast implants.
- Your medical records describe the presence of petechiae, but the SF-DCT cannot determine if it is diffuse, for example, by being in more than one area.
- Your medical records reflect that you were diagnosed with one of the immune mediated skin changes or rashes before you received your first breast implant. (You may still receive credit for another rash under Group 3, if it did not exist before your first breast implant.)
- The board certified rheumatologist or dermatologist failed to provide the statement that your qualifying rash did not exist before your first breast implant.



## **Immune-mediated Skin Change or Rash in Group 1 vs. Immune-mediated Skin Changes or Rashes in Group 3**

If you are credited with the Group 1 symptom of Immune-mediated Skin Changes or Rashes (any of the rashes), then you cannot use the Group 3 symptom of Other Immune-mediated Skin Change or Rash to qualify for GCTS.

These are considered duplicative symptoms and you can only receive credit in one group.

# Group 3 - Serologic Abnormalities

To receive credit for **Group 3 Serological Abnormalities**, you must submit the following:

1. Laboratory tests showing **ONE** of the following:
  - (a) Two positive ANA tests, i.e., greater than or equal to 1:40 (using Hep2).  
The tests must have been taken at least two months apart; **or**
  - (b) One or more positive ANA profile: Anti-DNA, SSA SSB, RNP, SM, Scl-70, centromere, Jo-1 PM-Scl, or double-stranded DNA (using ELISA with standard cutoffs); **or**
  - (c) anti-microsomal or anti-cardiolipin; **or**
  - (d) Rheumatoid Factor (RF) greater than or equal to 1:80; **and**
  
2. The physician who orders the laboratory test must state that you did not have that specific test with a positive finding before the date you received your first breast implant.

## Group 3 – Serologic Abnormalities

1. **ANA** - in Group 3, the ANA test results do not require that the result be outside of the performing laboratory's normal reference range. A titer of 1:40 can be counted in Group 3, regardless of the performing lab's reference range. For example: If the reference range indicates an ANA of 1:40 is within the laboratory's normal limits, it can still be credited, but only in Group 3.

2. **Other ANA profiles:** anti-DNA (single or double stranded is acceptable); SSA (stands for Smith surface antigen); SSB (single stranded binding); RNP (anti-ribonucleoprotein antibodies); SM (stands for Anti-Smith - not smooth, striated, or skeletal); Scl-70, Centromere (an antibody that reacts with centromeric protein); Jo-1 or PM-Scl; Double-stranded DNA (Much more accurate testing than single-stranded DNA). **All tests must use ELISA method with standard cutoffs.**

continued on next page

## Group 3 - Serologic Abnormalities

continued from prior page:

3. **Anti-microsomal** (an organ-specific antibody, which is directed against a thyroid microsomal antigen);
4. **Anti-cardiolipin** (antibody directed against cardiolipin).
5. **Positive Rheumatoid Factor (RF)** - RF must be equal to or greater than 1:80 or positive findings of Rheumatoid Factor measuring in serum concentrations (IU/ml), 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).

## Group 3 – Unacceptable proof for Serological Abnormalities

Common reasons why claimants receive a deficiency about the Group 3 symptom of Serologic Abnormalities:

- ANA laboratory results are less than 1:40.
- Rheumatoid Factor or other tests are within normal limits.
- ANA is reported as “abnormal” without a numeric value.
- Abnormal or elevated laboratory results existed prior to the date of the first breast implantation.
- Abnormal laboratory results are directly related to another cause or condition.
- The physician who ordered the test failed to provide the statement that your qualifying serological abnormality did not exist before your first breast implant.

## **Group 2 Serological Abnormalities vs. Group 3 Serological Abnormalities**

If you are credited with the Group 2 symptom of Positive ANA, then you cannot use the Group 3 symptom of Serological Abnormalities in Group 3 to qualify for GCTS.

These are considered duplicative symptoms and you can only receive credit in one group.

## Group 3 - Raynaud's Phenomenon

To receive credit for **Raynaud's Phenomenon**, you must submit **ALL** of the following:

1. Office notes documenting that your physician observed **ONE** of the following:
  - (a) two, cold-related color changes as a progression; **or**
  - (b) evidence of cold-related vasospasm; **or**
  - (c) digital ulceration resulting from Raynaud's phenomenon; **and**
2. The physician who observed the above condition must state that you did not have Raynaud's Phenomenon before the date you received your first breast implant.

## **Group 3 – Unacceptable proof of Raynaud's Phenomenon**

### **Common reasons why claimants receive a deficiency about Raynaud's Phenomenon:**

- There is only one color change observed by a physician.
- The physician who observed the two color changes did not make a reference that it was cold related.
- The physician who observed the Raynaud's failed to provide the statement that your Raynaud's Phenomenon did not exist before your first breast implant.



## Group 3 – Acceptable proof of Myalgias

**Myalgias** is a complaint of muscle pain. To receive credit for Myalgias, you must submit **ALL** of the following:

1. Office notes of an examination documenting tenderness to palpation in at least three muscles, each persisting for at least six months; **and**
2. The physician who performed the examination must state that the Myalgias did not exist before the date you received your first breast implant.

## Group 3 – Unacceptable proof of Myalgias

Common reasons why claimants receive a deficiency about the symptom of Myalgias:

- Medical records reflect a diagnosis of myalgias prior to the date of the first breast implantation.
- Medical records reflect a notation of muscle pain or myalgias without documenting the specific muscle.
- Medical records directly relate muscle pain to another cause or condition.
- Medical records reflect a diagnosis of trigger points or tender points prior to the date of the first breast implantation.
- Medical records reflect a diagnosis of Fibromyalgia prior to the date of the first breast implantation.
- The physician who documented the Myalgias on examination failed to provide the statement that your Myalgias did not exist before your first breast implant.

## Group 3 – Acceptable proof of Dry Mouth

To receive credit for **Dry Mouth**, you must submit **ALL** of the following:

1. Medical records documenting subjective complaints of dry mouth; **and**
2. Laboratory test results showing decreased parotid flow rate using Lashley cups (or any other objective test that measures saliva production) with less than 0.5 ml per five minutes; **and**
3. A statement from the doctor who performed the lab test stating that you are not taking any drugs known to cause dry mouth; **and**
4. A statement from the doctor who performed the test stating that you did not have dry mouth before the date you received your first breast implant

## Group 3 – Unacceptable proof of Dry Mouth

### Common reasons why claimants receive a deficiency about the symptom of Dry Mouth:

- The medical records reflect a history or complaints of dry mouth but no test results are submitted.
- The medical records directly relate dry mouth to another cause or condition.
- A diagnosis of Keratoconjunctivitis Sicca or dry mouth existed prior to the date of the first breast implant.
- The physician who documented the dry mouth failed to provide the statement that your dry mouth did not exist before your first breast implant.
- The physician who documented the dry mouth failed to provide the statement excluding drugs or medications known to cause dry mouth.

## Group 1 K-Sicca vs. Group 3 Dry Mouth

If you are credited with the Group 1 symptom of K-Sicca, Dry Eyes or Dry Mouth, then you cannot use the Group 3 symptom of Dry Mouth in Group 3 for GCTS.

These are considered duplicative symptoms and you can only receive credit in one group.

## 2. Types of Medical Records not acceptable for GCTS Claims

The following are common reasons why claimants receive a deficiency notice about their GCTS submission:

The claimant submitted a letter or other type of document other than a medical record or test result to document a finding or symptom of GCTS. You must submit the actual record and test results that document the finding or symptom. The following are not acceptable documents:

- Letters written by a physician to an attorney.
- Letters written to a physician from another physician, because it is not an actual medical record unless it is a consult report (see page 87).
- Letters written for the Dow Corning Settlement or any other settlement.
- Documents written to insurance companies.
- Documents written to the Social Security Administration.
- Form sheets listing findings or symptoms cannot be used to credit any finding or symptoms.
- Form sheets or checklists from an attorney.
- Billing statement listing the symptoms.

A doctor can submit a letter that clarifies or explains his/her office notes as long as it does not conflict with any information in the medical records and does not add new information that was not in the original medical record submitted.

## 2. Types of Medical Records for GCTS Claims- What about letters from one physician to another?

Letters written to a physician from another physician will be accepted, if it is a Consultation Report written to the referring treating physician and contains the report of the examination.

However, the Plan requires that all underlying medical records be submitted to establish the symptom. You may be required to submit additional information, if what is contained in the Consultation Report is not sufficient to credit the symptom.

### 3. Exclusion Statement Required For Specific Findings

If one of your eligible symptoms is either Polyarthrititis, Keratoconjunctivitis Sicca, Immune mediated Skin Changes or Rashes-Malar Rash Myositis -CPK, Peripheral Neuropathy or Polyneuropathy, or Dry Mouth, you must submit a statement from the doctor who documented this symptom excluding certain drugs or conditions as the cause of the symptom (see the specific Exclusion Statement listed under the requirements for each symptom).



## 4. 24 Month Rule for GCTS, Disease Option 2

To qualify for GCTS in Disease Option 2, all of your qualifying symptoms must have occurred within 24 months of each other. The Settlement Facility will look at the time frame that allows the claimant to qualify.

If you submit additional medical records to correct a deficiency notice that you receive from the Settlement Facility, then the symptom subject to the deficiency does not have to fall within the same 24 month time frame as the other credited symptoms. Also, new symptoms documented in additional medical records submitted in response to a deficiency notice do not have to fall within the same 24 month time frame as the other credited symptoms.

## 5. 5 Year Filing Deadline for GCTS, Disease Option 2 Claims

To qualify for GCTS in Disease Option 2, you must submit your Disease claim to the Settlement Facility (or have submitted it to the MDL 926) within 5 years from the date your qualifying symptoms were documented.

If you submitted your Disease claim form to the MDL 926 as part of either the original global settlement in 1994 or the Revised Settlement Program, then the Settlement Facility will look at either the MDL submission date or the SF-DCT submission date that will allow the claimant to qualify.

## 5. 5 Year Period Tolled From May 15, 1995 to May 31, 2004

The time period that Dow Corning was in bankruptcy (May 15, 1995 to May 31, 2004) will not be used to calculate whether you filed your claim within 5 years of your qualifying symptoms. For example, if your qualifying symptoms were documented on May 1, 1994, then your time period to file a claim runs from that date, May 1, 1994, to May 14, 1995 (the day before Dow Corning filed for bankruptcy. This is a total of 12.5 months. It begins to run again on June 1, 2004, the date the Plan became effective. Your deadline to file a Disease Option 2 claim in this example is 47.5 months from June 1, 2004, or May 15, 2008.

Your qualifying symptoms must have occurred within a single 24 month period within this 5 year period.

## 5. Failure to meet the 24 month / 5 year time requirement:

If you do not file your claim within the 5 years of the date your qualifying symptoms are documented and your symptoms do not occur within a single 24 month time frame within this 5 year period, then you cannot be paid for a Disease Option 2 claim. You may still be compensated in Disease Option 1 if you otherwise qualify based on your symptoms and disability.

## 6. Pre-existing Symptoms are not acceptable in GCTS, Disease Option 2

To meet the Plan's requirements, your physician must state in a letter or medical records that you did not have any of your qualifying symptoms before you received your first breast implant.

Acceptable ways for your physician to document that you did not have pre-existing symptoms:

- Based on history, she did not have (qualifying finding or symptom) before she received her first breast implant; or
- The patient first experienced (qualifying symptom) 2 years after she received her first breast implant; or
- The patient did not have (qualifying symptom) until after she received her first breast implant; or
- The patient's (qualifying finding or symptom) started 3 years after she received her first breast implant.

# SF-DCT INFORMATION FOR GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS) CLAIMS

## OPTION 2- Compensation

# Compensation Levels in GCTS

For compensation at Level A - \$110,000 (U.S., Class 5) (see page \_\_\_ for the combination of findings required for Level A)

For compensation at Level B - \$75,000 (U.S., Class 5) (see page \_\_\_ for the combination of findings required for Level B)

If Premium Payments are approved by the District Court, approved GCTS claimants could receive an additional payment of up to 20% of their Base Payment:

Level A – Premium Payment of up to \$22,000 (U.S., Class 5)

Level B – Premium Payment of up to \$15,000 (U.S., Class 5)