

SF-DCT INFORMATION FOR SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) CLAIMS

OPTIONS 1 & 2

Systemic Lupus Erythematosus (SLE)

Systemic Lupus Erythematosus (SLE) is a condition of chronic inflammation when the body's tissues are attacked by its own immune system. SLE can affect a variety of areas of the body and can cause disease of the skin, lungs, kidneys, joints, blood, and brain. (1)

The American Rheumatism Society established 11 criteria for doctors to consider in diagnosing SLE. When a person has four or more of these criteria, the diagnosis of SLE is strongly suggested. (1) These same 11 criteria have been adopted in the Dow Corning Plan; however, to qualify for compensation, you must meet additional requirements as set forth in this document.

(1) Source: Website: www.MedicineNet.com

Types of Lupus

Discoid Lupus – this is when only the skin is involved. Discoid Lupus, by itself, is not compensable in the Dow Corning Plan. It is, however, an eligible symptom for General Connective Tissue Symptoms (GCTS) and SLE.

Systemic Lupus – this is when internal organs are involved. Systemic Lupus is compensable in the Dow Corning Plan in Disease Option 1 or Disease Option 2.

Mild Lupus – Mild Lupus is defined in the Dow Corning Plan as SLE that does not require regular medical attention including doctor visits and regular prescription medications. Mild Lupus is eligible for Disease Option 1, however, it is not eligible for compensation in Disease Option 2.

What is the difference between Disease Option 1 and Disease Option 2?

SLE is compensable in Disease Option 1 or Option 2.

If you have a diagnosis of SLE from a Board Certified Rheumatologist, and you document four of the 11 criteria for SLE, and all of your qualifying symptoms occurred within a 24 month period, then generally your claim will be placed in Disease Option 2. If, however, you do not meet the Disease Option 2 SLE criteria, the Settlement Facility will review your claim to determine if it qualifies for Disease Option 1 SLE or, if applicable, for Atypical Connective Tissue Disease (ACTD) in Disease Option 1.

A chart summarizing key differences between Disease Option 1 and 2 SLE claims is on page 105.

Systemic Lupus Erythematosus (SLE) CLAIMS

DISEASE OPTION 2
INFORMATION

To qualify for SLE in Disease Option 2, you must submit the following documents:

To submit a claim for SLE in Disease Option 2, you must meet ALL of the criteria listed below:

- 1) A diagnosis of Systemic Lupus Erythematosus (SLE) (see pages 7-8); **and**
- 2) made by a Board Certified Rheumatologist (BCR) (see page 9); **and**
- 3) based upon personal examination by the BCR. (see page 10); **and**

In addition, you must submit the following documents:

- 4) All medical records (including lab reports) that document your qualifying symptoms and the diagnosis of Systemic Lupus Erythematosus; **and**
- 5) All your qualifying symptoms must have occurred within a 24 month period (see pages 59-62); **and**
- 6) 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 page (60-61) for additional information); **and**
- 7) A statement from the BCR that you did not have any of the qualifying symptoms of SLE before you received your first breast implant (see pages 63-64); **and**
- 8) If you qualify for SLE Level C, you must submit a statement from the BCR that you do not have Mild Lupus and your medical records must document the treatment you are receiving for your SLE symptoms (see pages 65-66). If you qualify for SLE Level A or B, you do not need to submit this statement (see page 65).

1a) SLE Disease Option 2: You must have a diagnosis of Systemic Lupus Erythematosus from a Board Certified Rheumatologist (BCR)

The following are acceptable ways for a BCR to document a Diagnosis of SLE:

- Mrs. Jones has Systemic Lupus Erythematosus (or SLE).
- Mrs. Jones has the symptoms of SLE, and therefore, I conclude that she has Systemic Lupus Erythematosus.
- Mrs. Jones satisfies the symptom criteria according to the 1982 criteria from the American College of Rheumatology for a diagnosis of Systemic Lupus Erythematosus.
- I have treated Mrs. Jones for SLE since 2005.
- A notation in the BCR's medical record stating, "Lupus" or "Systemic Lupus Erythematosus" or the abbreviation "SLE".

1b) Common problems with crediting a diagnosis of SLE in Disease Option 2

Common reasons why claimants receive a deficiency about the diagnosis of Systemic Lupus Erythematosus in Disease Option 2 include:

- The diagnosis is written by a physician who is not board certified in Rheumatology (BCR).
- The diagnosis is based on a claimant's history, and not the physician's actual assessment.
- The diagnosis is written based on lab reports or bill statements for payment purposes.
- The diagnosis refers to the Settlement Plan criteria, instead of the physician's clinical opinion made for purposes of treating the claimant. A diagnosis made for medical-legal purpose is not an acceptable diagnosis of Systemic Lupus Erythematosus. For example, the BCR states "This is intended to be a medical-legal diagnosis and not intended to serve as a clinical diagnosis."
- The diagnosis is written as "Lupus-type" or "SLE-like" disease.
- The diagnosis is written as "possible," "probable" or "most likely Lupus" It must affirmatively state that you have Systemic Lupus Erythematosus.
- A diagnosis of SLE is from a physician whose credentials have expired in rheumatology or who is not yet board certified in rheumatology.
- A BCR gives an affirmative diagnosis of SLE, but the same board certified rheumatologist later runs more tests and concludes that the claimant does not have the disease.
- The letter containing the diagnosis is not signed by the BCR.

2) The diagnosis must be made by a Board Certified Rheumatologist (BCR)

To qualify for Disease Option 2 Systemic Lupus Erythematosus, you must have been examined and received a diagnosis from a Board Certified Rheumatologist.

The Settlement Facility cannot accept a diagnosis from any other specialty in Disease Option 2, such as an Internist or family doctor.

3a) The diagnosis must be based on a personal examination by the BCR

You must submit the office records of the examination as well as all other medical records and lab reports that document the qualifying symptoms.

- The office records can be written, typed, or dictated.
- A consultation report from a BCR written to a referring physician will count as the underlying exam.
- A consultation report from a BCR written to an attorney will not count as the underlying exam.
- The diagnosis cannot be based on patient history or a review of your records.

3b) Does the BCR have to find all of the symptoms on one exam?

No, the BCR does not have to find all of the SLE symptoms during one exam.

If (s)he has reviewed your medical records and concludes that you have Systemic Lupus Erythematosus based on the exam, then the Settlement Facility will credit the exam.

4) What are the symptoms of SLE Disease in Option 2?

In addition to a diagnosis of SLE by a Board-Certified Rheumatologist, you must submit **ALL** of the medical records (including lab reports) that establish any **FOUR** of the following symptoms:

- a. Malar Rash (pages 13-16)
- b. Discoid Rash (pages 17-20)
- c. Photosensitivity (pages 21-23)
- d. Oral Ulcers (pages 24-26)
- e. Arthritis (pages 27-29)
- f. Serositis (pages 30-34)
- g. Renal Disorder (pages 35-37)
- h. Neurological Disorder (pages 38-42)
- i. Hematologic disorder (pages 43-52)
- j. Immunologic disorder (pages 53-54)
- k. Antinuclear Antibody (pages 55-58)

CITE: Annex-A 102 and
Disease Claimant Information Guide at Tab 1

4a) Eligible Symptom: MALAR RASH

Malar Rash is defined as fixed erythema (redness), 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 criteria notes eminences (which is referring to the cheekbone). This requires the presence of the rash on both sides of the face, cheek, or cheekbones. It is often described as a butterfly rash because the rash is shaped like a butterfly (the wings are beneath both eyes and the body of the butterfly covers the bridge of the nose).

The rash can appear and fade without any pain or itching and is Photosensitive (i.e., sensitive to sunlight).

4a. MALAR RASH - acceptable proof

To credit the symptom of MALAR RASH, the office note of the exam must show ONE of the following:

- Malar rash; or
- Butterfly rash or butterfly-shaped rash; or
- Malar erythema; or
- Rash on cheeks and bridge of nose; or
- Rash on malar eminences; or
- Telangiectasia in a malar distribution with fixed erythema.

The description can be found on physical examination or found in the history portion of the examination.

4a. MALAR RASH - unacceptable proof

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)

4a. MALAR RASH - unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Malar Rash include:

- The symptom of Malar Rash existed before the date you received your first breast implant.
- The Malar rash is described on a part of the body other than the face.
- The medical records reflect that you have a skin condition such as rosacea, eczema, psoriasis, acne, or dermatitis and not a malar rash.
- The medical records reflect facial flushing, malar flush or blush, or facial redness or erythema.
- The medical records reflect a medication-induced rash.
- The rash is described on only one cheek. The rash must be on both cheeks.
- The office note of the examination reflecting the symptom of Malar Rash was not submitted.

4b. Eligible Symptom: DISCOID RASH

Discoid Rash is described as erythematous (redness), raised patches with adherent keratotic scaling (hard, horny-growth of the skin), and follicular plugging (opening of the hair follicle with hard plugs of keratin); atrophic scarring may occur in older lesions.

Discoid lesions are small, flaky red rashes that are named for their coin or oval (disc) shape. The rashes are most common on the face but can also appear on the trunk, arms and legs.

4b. DISCOID RASH - acceptable proof

To credit the symptom of DISCOID RASH, your records must contain ONE of the following:

1. The office notes of an exam that reflects that the rash was observed by a physician, and contains a description of BOTH keratotic scaling and follicular plugging; or
2. A skin biopsy report that reflects a discoid rash or discoid lesion, discoid lupus, or a diagnosis of an autoimmune type rash (provided that there is a sufficient description of keratotic scaling and follicular plugging).

4b. Discoid Rash

The Discoid Rash can be documented by any physician provided that the physician observed the rash on exam.

4b. DISCOID RASH – unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Discoid Rash:

- The symptom of Discoid Rash existed before the date you received your first breast implant.
- The notation of Discoid Rash is by history only.
- The rash that does not fit the description of Discoid Rash but describes something else such as eczema, dermatitis, or psoriasis.
- The records show an allergic skin reaction or rash caused by soaps, chemicals, or other irritants.
- There is a diagnosis of Discoid Rash by a physician, but the corresponding biopsy report or underlying office record reflects another condition.
- The skin biopsy report documents other “lupus rashes” but does not state or describe a Discoid Rash.
- The office note or biopsy report that reflects the symptom of Discoid Rash was not submitted.

4c. Eligible symptom: PHOTSENSITIVITY

Photosensitivity is defined as a skin rash resulting from an unusual reaction to the sun.

4c. PHOTSENSITIVITY - acceptable proof

To credit the symptom of PHOTSENSITIVITY, your medical records must reflect ONE of the following:

1. Office notes that document a patient history of sun sensitivity; or
2. A photosensitive rash that is observed by a physician; or
3. Office notes that contain a diagnosis of photosensitivity or photosensitive rash by a physician; or
4. Office notes that describe an existing rash that gets worse when exposed to the sun.

4c. PHOTSENSITIVITY - unacceptable proof

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

- ✘ The symptom of Photosensitivity existed before the date you received your first breast implant.
- ✘ Photosensitivity is described as “photophobia,” which is light sensitivity that affects the eyes and not the skin.
- ✘ The medical records describe sunburn.
- ✘ The office note of the examination reflecting the symptom of Photosensitivity was not submitted.

4d. Eligible Symptom: ORAL ULCERS

Oral Ulcers are an oral or nasopharyngeal ulceration (sores or open wounds in the mouth, nose or throat), usually painless, observed by a physician.

Any physician can document the presence of oral ulcers provided that the physician observed the ulcers on exam. A dentist can document oral ulcers in the mouth.

4d. ORAL ULCERS - acceptable proof

To credit the symptom of Oral Ulcers, the physician who observed the ulcer may describe it in any of the following ways:

- ✓ Aphthous or Aphthae
- ✓ Canker sore
- ✓ Oral lesion
- ✓ Mouth ulcer
- ✓ Mucosal erosions found in the nose or mouth
- ✓ Buccal ulcer, lesion, sore, or erosion

4d. ORAL ULCERS - unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Oral Ulcers:

- ✘ The symptom of Oral Ulcers existed before the date you received your first breast implant.
- ✘ The Oral Ulcers are by patient history only. The Oral Ulcer must be observed by a physician or dentist.
- ✘ The Oral Ulcers are caused by a specific condition such as oral herpes.
- ✘ The medical records reflect only mouth or gum soreness.
- ✘ The Oral Ulcers are caused by dentures or braces.
- ✘ The medical records reflect stomach, peptic, or intestinal ulcers.

4e. Eligible Symptom: ARTHRITIS

Arthritis is a condition characterized by pain and swelling in the joints, which may cause damage to the joints of the body. There are many types of arthritis; however, you cannot receive credit for Arthritis if your records show that it is “erosive arthritis” or “Rheumatoid Arthritis.”

4e. ARTHRITIS - acceptable proof

To receive credit for ARTHRITIS, your records must reflect ALL of the following:

1. A diagnosis of arthritis or reference to arthritis by a physician; and
2. The office note of the examination must reflect evidence of swelling, tenderness, or effusion of TWO or more peripheral joints. Tenderness is defined as bone pain when touched. Swelling or effusion is defined as an increase in fluid in the joint space. (Peripheral joints include shoulders, hips, feet, knees, toes, ankles, elbows, hands, and fingers.); and
3. A statement from the BCR that the arthritis is non-erosive. (The treating physician who found the symptom of arthritis may also give this statement.)

4e. ARTHRITIS - unacceptable proof

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

- ✘ The symptom of Arthritis existed before the date you received your first breast implant.
- ✘ The medical records reflect a diagnosis of arthritis, but there are no office records that show swelling, tenderness or effusion of two or more peripheral joints.
- ✘ The joint areas noted are described as myalgias or tenderness in muscles and not actual joint swelling or tenderness.
- ✘ The claimant has a diagnosis of classical Rheumatoid Arthritis or another type of erosive arthritis.
- ✘ Pain is located in the joints of the spine, back or neck; these are not peripheral joints.
- ✘ Hand swelling will not be credited as joint swelling of the fingers.
- ✘ The BCR or treating physician did not make the statement that the arthritis is non-erosive.
- ✘ X-rays that show that the arthritis is erosive.
- ✘ The office note of the exam that reflects the symptom of Arthritis was not submitted.

4f. Eligible Symptom: SEROSITIS

Serositis is the inflammation of serous tissues of the body. To receive credit for the symptom of SEROSITIS, your medical records must reflect that you have one of the following conditions:

Pleuritis or Pleurisy (inflammation of the pleura, the lining of the pleural cavity surrounding the lungs), or

Pericarditis (inflammation of the pericardial sac surrounding the heart).

4f. SEROSITIS - acceptable proof for Pleuritis or Pleurisy

To receive credit for the symptom of SEROSITIS – Pleuritis, your records must reflect ONE of the following:

1. Office notes that show recurring Pleuritis or pleurisy with a very descriptive account of pleuritic pain. (This type of pain is usually described as sharp and is felt upon taking a deep breath.); or
2. Office notes that show Pleuritis or pleurisy with a pleural friction rub heard by a physician; or
3. X-ray report with evidence of pleural effusion.

4f. SEROSITIS - unacceptable proof for Pleuritis

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

- ✘ The symptom of Pleuritis existed before the date you received your first breast implant.
- ✘ Atypical chest pain, not pleuritic in nature, such as angina.
- ✘ A diagnosis of pleural effusion, but with normal diagnostic tests.
- ✘ The condition of costochondritis is not the same as pleurisy.
- ✘ The office note or diagnostic test that reflects the symptom of Pleuritis was not submitted.

4f. SEROSITIS - acceptable proof for Pericarditis

To receive credit for **SEROSITIS – Pericarditis**, your records must reflect **ONE** of the following:

1. A physician must make the diagnosis of pericarditis **and** you must have an (ECG) electrocardiogram that confirms the diagnosis of Pericarditis; **or**
2. Office notes that show Pericarditis with a pericardial friction rub heard on examination; **or**
3. An x-ray, echo (echocardiogram), or other radiology test with evidence of pericardial effusion.

4f. SEROSITIS - unacceptable proof for Pericarditis

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

- ✘ The symptom of Pericarditis existed before the date you received your first breast implant.
- ✘ There is no diagnosis of Pericarditis, pericardial rub, or pericardial effusion in the records.
- ✘ There is a diagnosis of pericardial effusion but diagnostic tests show normal results.
- ✘ The office note or diagnostic report that reflects the symptom of Pericarditis was not submitted.

4g. Eligible Symptom: RENAL DISORDER

Urine tests are used to diagnose renal (kidney) disease. Two important indicators are Persistent Proteinuria (abnormal levels of protein the urine) and Cellular Casts (urinary sediments).

4g. RENAL DISORDER – acceptable proof

To receive credit for the symptom of RENAL DISORDER, you must submit laboratory reports documenting ONE of the following:

1. Persistent Proteinuria documented by a 24-hour urine test showing protein greater than 0.5 grams/day; or
2. Protein Proteinuria documented by a urinalysis showing greater than 3+ urine protein (more than 1 time); or
3. Cellular Casts documented by a urinalysis showing any of the following casts: Red cell, Hemoglobin, Granular, Tubular, Mixed, or Hyaline.

4g. RENAL DISORDER - unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Renal Disorder:

- ✘ The symptom of Persistent Proteinuria or Cellular Casts existed before the date you received first breast implant.
- ✘ The laboratory report refers to red blood cells (RBCs) in the urine; it must find the presence of red blood cell casts.
- ✘ The urinalysis reflects trace protein or less than or equal to 3+ urine protein.
- ✘ The 24-hour urine test reflects less than or equal to 0.5 grams of protein per day.
- ✘ The laboratory reports reflecting Persistent Proteinuria or Cellular Casts were not submitted.

4h. Eligible Symptom: NEUROLOGIC DISORDER

NEUROLOGIC DISORDER for SLE in Disease Option 2 is defined as the presence of SEIZURES in the absence of offending drugs or known metabolic derangements.

Seizures are episodes of uncontrolled electrical activity in the brain. These abnormal electrical disturbances may lead to involuntary jerking, spasms, rhythmic contraction and relaxation of certain muscle groups, or a sudden loss of consciousness or change in a state of consciousness (1),

(1) Source: Website: www.MedicineNet.com

4h. NEUROLOGIC DISORDER: Seizures - acceptable proof

To receive credit for the symptom of NEUROLOGIC DISORDER Seizure, your records must reflect ALL of the following:

1. Physician office records that confirm a diagnosis of Seizures; and
2. Evidence of treatment for Seizures, such as office notes and medications; and
3. The seizures must be in the absence of certain metabolic conditions; and
4. The seizures must be in the absence of certain drugs.

4h. NEUROLOGIC DISORDER – metabolic conditions

Certain metabolic conditions will prevent claimants from receiving credit for the symptom of Neurologic Disorder:

1. **Uremia**- the presence of excessive amounts of urea in the blood, which may be a sign of kidney disease or failure. (1)
2. **Ketoacidosis**- ketosis is the accumulation of substances called ketone bodies in the blood. Acidosis is increased acidity of the blood. (1)
3. **Hypoglycemia**- a condition marked by lower than normal level of sugar (glucose) in the blood.
4. **Electrolyte Imbalances** (decreased or elevated) will prevent claimants from receiving credit for the Neurologic Disorder (the following are examples of electrolytes found in your blood:
 - × Magnesium (Mg⁺)
 - × Sodium (Na⁺)
 - × Calcium (Ca⁺)
 - × Potassium (K⁺)
 - × Chloride (Cl⁻)

(1) Source: Website: www.MedicineNet.com

4h. Neurologic Disorder – drugs or medications

Certain drugs or medications can cause seizures. If you are taking any of the following medications, then the SF-DCT may not credit you with the symptom of Neurologic Disorder:

- Alprazolam (xanax)
- Antibiotics
- Clorazepate (tranxene)
- Diazepam (valium)
- Lorazepam (ativan)
- Meperidime (demerol)
- Haloperidol (haldol)

4h. Neurologic Disorder - unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Neurologic Disorder:

- ✘ The symptom of Neurologic Disorder existed before the date you received your first breast implant.
- ✘ The patient provides a history of Seizures but there are no confirming medical records.
- ✘ The Seizures are caused by non-qualifying conditions such as brain tumors or injury (trauma to the head).
- ✘ The claimant has been diagnosed with a metabolic condition (see page 40).
- ✘ The claimant is on certain drugs that are known to cause seizures (see page 41).

4i. Eligible Symptom: HEMATOLOGIC DISORDER

A Complete Blood Count (CBC) is used to measure the number of red and white blood cells and platelets and to detect abnormalities in the structure, function, or the blood-clotting mechanism of the blood cell.

4i. HEMATOLOGIC DISORDER – acceptable proof

To receive credit for the symptom of HEMATOLOGIC DISORDER, laboratory report(s) must reflect that you have ONE of the following blood disorders:

1. Hemolytic Anemia – anemia due to the abnormal breakdown of red blood cells resulting in a decreased number of red blood cells (see pages 45-46); or
2. Leukopenia – a decrease in the number of circulating white blood cells in the blood (see pages 47-48); or
3. Lymphopenia – a condition of decreased lymphocytes (white blood cells) in the blood (see pages 49-50); or
4. Thrombocytopenia – the presence of relatively few platelets in the blood (see pages 51-52).

4i. HEMATOLOGIC DISORDER: Hemolytic Anemia - acceptable proof

To receive credit for HEMOLYTIC ANEMIA, you must submit the lab report of a Complete Blood Count (CBC) that shows ALL of the following:

1. an abnormal decrease in red blood cells (RBC); and
2. an abnormal decrease in hemoglobin (Hgb); and
3. an abnormal decrease in hematocrit (Hct); and
4. an increase in **reticulocytes**. The reticulocyte count must be present with the CBC report.

“Abnormal” means that the lab results are outside the reference range for the reporting laboratory.

4i. HEMATOLOGIC DISORDER: Hemolytic Anemia - unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Hematologic Disorder - Hemolytic Anemia:

- ✘ The symptom of Hemolytic Anemia existed before the date you received your first breast implant.
- ✘ The medical records reflect a diagnosis of hemolytic anemia, but the laboratory report does not show a decrease in Hemoglobin (Hgb) or Hematocrit (Hct), and there is no increase in the reticulocyte count (retic count).
- ✘ The laboratory report does not contain a reticulocyte count (retic count).
- ✘ The laboratory report of the CBC was not submitted.

4i. HEMATOLOGIC DISORDER: Leukopenia – acceptable proof

To receive credit for Leukopenia, you must submit **TWO** laboratory reports that reflect an abnormal decrease in white blood cells (WBC). Each laboratory report must show a white blood cell (WBC) count of: Less than 4,000 mm³ or 4.0.

4i. HEMATOLOGIC DISORDER: Leukopenia - unacceptable proof

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

- ✘ The symptom of Leukopenia existed before the date you received your first breast implant.
- ✘ Only one laboratory report reflects Leukopenia.
- ✘ Only one laboratory report was submitted.
- ✘ The white blood cell count was equal to or greater than 4,000 mm³ or 4.0.
- ✘ The laboratory reports that document Leukopenia were not submitted.

4i. HEMATOLOGIC DISORDER: Lymphopenia – acceptable proof

To receive credit for LYMPHOPENIA, you must submit **TWO** laboratory reports that reflect an abnormal decrease in lymphocytes. Each laboratory report must show a lymphocyte cell count of: Less than 1,500 mm³ or 1.5.

4i. HEMATOLOGIC DISORDER: Lymphopenia - unacceptable proof

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

- ✘ The symptom of Lymphopenia existed before the date you received your first breast implant.
- ✘ Only one laboratory report reflects Lymphopenia.
- ✘ Only one laboratory report was submitted.
- ✘ The lymphocyte count was equal to or greater than 1,500 mm³ or 1.5.
- ✘ The laboratory reports that document Leukopenia were not submitted.

4i. HEMATOLOGIC DISORDER: Thrombocytopenia – acceptable proof

To receive credit for the symptom of THROMBOCYTOPENIA, you must submit ONE laboratory report that reflects an abnormal decrease in platelets (PLT). The laboratory report must show a platelet (PLT) cell count of: Less than 100,000mm³.

Thrombocytopenia must have occurred in the absence of drugs known to cause this condition including but not limited to:

- quinidine
- sulfa preparations
- oral anti-diabetics
- gold salts
- rifampin
- non-steroidal anti-inflammatory drugs (NSAIDS)

4i. HEMATOLOGIC DISORDER: Thrombocytopenia - unacceptable proof

Common reasons why claimants receive a deficiency notice for the symptom of Thrombocytopenia:

- ✘ The symptom of Thrombocytopenia existed before the date you received your first breast implant.
- ✘ The laboratory report that documents Thrombocytopenia was not submitted.
- ✘ The platelet count was equal to or greater than $100,000\text{mm}^3$.
- ✘ At the time the test was performed, your records reflect that you were taking a drug or medication that causes a decrease in platelets.

4j. Eligible Symptom: Immunologic Disorder – acceptable proof

Tests can be done for certain antibodies to assist in establishing a diagnosis of SLE. To receive credit for the symptom of IMMUNOLOGIC DISORDER, you must submit **ONE** laboratory report documenting ONE of the following:

- Positive LE cell preparation; **or**
- Anti-DNA - Antibodies to native DNA (the protein that makes up the body's genetic code) in abnormal titer or abnormal units per ml; **or**
- Anti-SM - Antibodies to the Sm nuclear antigen; **or**
- Anti-SSA (Ro); **or**
- A false positive serologic test for syphilis. It must be false positive for at least 6 months, **and** confirmed false positive by a treponema pallidum immobilization or fluorescent treponemal antibody absorption test.

4j. Immunologic Disorder - unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Immunologic Disorder:

- ✘ The abnormal laboratory test existed before the date you received your first breast implant.
- ✘ The lab report shows a negative result for any of the tests.
- ✘ The Anti-DNA test result is for a single strand test. It must be from a double strand test.
- ✘ The Anti-Sm test is positive; however, it does not stand for Anti-Smith, but instead refers to anti-smooth, anti-striated, or anti-skeletal, which are not acceptable.
- ✘ The false-positive test for syphilis was not confirmed by one of the two required methods.
- ✘ The false-positive test for syphilis was for less than 6 months.
- ✘ You have a confirmed diagnosis of syphilis.
- ✘ The laboratory report that reflects the abnormal test for Immunologic Disorder was not submitted.

4k. Eligible Symptom: **POSITIVE ANTINUCLEAR ANTIBODY (ANA)**

Antinuclear antibodies (ANAs) are unusual antibodies, detectable in the blood, that have the capability of binding to certain structures within the nucleus of the cells. The ANA test measures the pattern and amount of autoantibody, which can attack the body's tissues as if they were foreign material. (1)

(1) Source: Website: www.MedicineNet.com

4I. POSITIVE ANTINUCLEAR ANTIBODY (ANA) - acceptable proof

To receive credit for the symptom of POSITIVE ANA, you must submit ONE laboratory report that reflects a positive (abnormal) ANA result. The following are examples of abnormal results that are acceptable by the SF-DCT:

- If the ANA pattern is speckled, then the result must be equal to or greater than 1:40.
- If the ANA pattern is homogenous, then the result must be equal to or greater than 1:80.
- If the ANA pattern is nucleolar, then the result must be equal to or greater than 1:20.
- If the ANA pattern is smooth, then the result must be equal to or greater than 15 iu (iu = international units)

4I. POSITIVE ANTINUCLEAR ANTIBODY (ANA) – drugs or medications

Certain drugs or medications may cause a positive ANA result and, in these situations, the symptom cannot be credited. Some of the most common drugs that may induce or cause a Positive ANA are anti-hypertensives (medications used to treat high blood pressure) such as:

- Hydrochlorothiazide (HCTZ)
- Metoprolol (Lopressor)
- Captopril (Capoten)
- Atenolol (Tenormin)
- Enalapril (Vasotec)
- Dyazide (Maxide)

4k. POSITIVE ANTINUCLEAR ANTIBODY (ANA) – unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Positive ANA:

- ✘ The symptom of Positive ANA existed before the date you received your first breast implant.
- ✘ The ANA results were negative or normal.
- ✘ There was no pattern noted.
- ✘ The laboratory report that documents the symptom of Positive ANA was not submitted.
- ✘ At the time the test was performed, the claimant was taking a drug or medication that causes an elevated ANA result.

5) 24 Month Rule for Disease Option 2 Claims

To qualify for Disease Option 2 Systemic Lupus Erythematosus, 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.

6a) 5 Year Filing Deadline for Disease Option 2 Claims

To qualify for Disease Option 2 Systemic Lupus Erythematosus, you must submit your Disease claim to the Settlement Facility (or have submitted it to the MDL 926) within 5 years from the date you were diagnosed with SLE.

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.

6b) 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.

6c) 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.

7a) Statement from your Board Certified Rheumatologist that you did not have any qualifying symptoms of SLE before you received your first breast implant

To qualify for SLE in Disease Option 2, you must submit a statement from your Board Certified Rheumatologist that you did not have any qualifying symptoms of SLE before the date you received your first breast implant. In other words, your BCR must provide a statement that your SLE symptoms were not pre-existing. (This is called the Not Pre-existing Statement.) Acceptable ways to state this include:

- Based on patient history, the patient did not have any symptoms of Systemic Lupus Erythematosus before the date she received her first breast implant.
- The patient first experienced symptoms of SLE after she received her first breast implant.
- The patient did not have any symptoms of SLE until after she received her first breast implant.
- The patient's SLE symptoms started after she received her first breast implant.

7b) “Not Pre-existing Statement” – unacceptable proof

Common reasons why claimants receive a deficiency regarding the “Not Pre-existing Statement” include:

- The patient did not have SLE before she received her first breast implant. (This is not acceptable, because this only affirms that the SLE diagnosis did not exist and not that the specific qualifying SLE symptoms did not exist before you received your first breast implant.)
- The physician who wrote the Not Pre-existing Statement is not the diagnosing BCR.
- You have a **diagnosis** of SLE prior to the date you received your first breast implant. This will preclude you from receiving compensation for SLE in Disease Option 2. If you have a **symptom** of SLE prior to the date you received your first breast implant, then you may still qualify for SLE in Disease Option 2; however, the SF-DCT cannot credit this symptom. If your medical records reflect that you had 4 of the 11 symptoms of Systemic Lupus Erythematosus prior to the date you received your first breast implant but you were not diagnosed with SLE, the claim will be reviewed with the Claims Administrator.

8a) If you qualify for SLE Level C (Disease Option 2), you must submit a statement that you do not have Mild Lupus (the “Exclusion Statement”).

The Settlement defines Mild Lupus as lupus that does not require regular physician visits and prescription medications. If you apply or qualify for SLE Level C, then you must submit a statement from your Board Certified Rheumatologist that you do not have Mild Lupus (the “Exclusion Statement”) and your medical records must document the treatment you are receiving for your SLE symptoms. The reason for this is because Mild Lupus is not eligible for compensation in Disease Option 2. If you qualify for SLE Level A or B as described below, then this provision does not apply to you.

1. **EXCLUSION STATEMENT IS REQUIRED:**

- If there is a diagnosis of SLE, you document at least four qualifying symptoms, your Board Certified Rheumatologist must state in a letter that you do not have Mild Lupus and your medical records must show regular prescription medications and physician visits for the treatment of your credited SLE symptoms.

2. **EXCLUSION STATEMENT IS NOT REQUIRED:**

- If there is a diagnosis of SLE, you document at least four qualifying symptoms, and you have renal involvement or one of the conditions as set forth on pages 70 thru 81 sufficient to qualify you for SLE Level A or Level B, then the SF-DCT can infer that you do not have Mild Lupus and you do not need to submit an “Exclusion Statement.”

8b) Mild Lupus – unacceptable proof

Common reasons why claimants receive a deficiency about the Exclusion Statement for Systemic Lupus Erythematosus in Disease Option 2 include:

- The statement submitted is written too generically such as stating, “The listed exclusions do not apply.” It must state that you do not have Mild Lupus.
- The statement from your Board Certified Rheumatologist states that you do not have Mild Lupus; however, your records do not reflect any ongoing treatment for your qualifying SLE symptoms.
- The statement from your Board Certified Rheumatologist states that you do not have Mild Lupus, but your medical records reflect that you are being treated for a condition that is not Lupus, such as diabetes or fibromyalgia.
- The Board Certified Rheumatologist states that you do have Mild Lupus.

SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) CLAIMS

DISEASE OPTION 2
COMPENSATION

Compensation for Disease Option 2 Systemic Lupus Erythematosus (SLE)

Compensation for SLE in Disease Option 2 is based on the severity of your illness. Your Board Certified Rheumatologist does not have to assign a compensation level for you in Disease Option 2.

LEVEL A – Base Payment of \$250,000 (Class 5) - Death resulting from SLE or severe chronic renal involvement manifested by a glomerular filtration rate of less than 50 percent of the age and gender adjusted norm, as measured by an adequate 24-hour urine specimen collection. (see pages 70-71 for more information).

LEVEL B – Base Payment of \$200,000 (Class 5) - SLE with involvement of one of the following conditions:

Glomerulonephritis, Seizures, Lupus psychosis, Myocarditis, Pneumonitis, Thrombocytopenic purpura, Hemolytic anemia, Severe granulocytopenia or Mesenteric vasculitis. (see pages 72-81 for more information).

LEVEL C – Base Payment of \$150,000 (Class 5) - A diagnosis of SLE as required in the Plan that does not involve the findings in Levels A or B above (see page 82 for more information).

Premium Payments for Disease Option 2 Systemic Lupus Erythematosus (SLE)

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

Level A – Premium Payment of up to \$50,000 (Class 5)

Level B – Premium Payment of up to \$40,000 (Class 5)

Level C – Premium Payment of up to \$30,000 (Class 5)

Disease Option 2 Systemic Lupus Erythematosus Level A - Death related to SLE, \$250,000 (Class 5)

To qualify for Level A based on death resulting from SLE, you must submit ONE of the following types of documents:

- A death certificate that indicates that the primary or secondary cause of death is related to SLE or one of the approved SLE symptoms; or
- An autopsy report that indicates the cause of death is related to SLE or one of the approved SLE symptoms; or
- A letter and/or medical records (hospital records, physician office records up to the time of death, nursing home records) from the Board Certified Rheumatologist that directly relate the primary or secondary cause of death is related to SLE or one of the approved SLE symptoms.

Level A based on a claimant's death can be approved without a death certificate or autopsy report. The claimant's death cannot be caused by any other disease or condition.

Disease Option 2 Systemic Lupus Erythematosus (SLE) Level A - Severe Chronic Renal Involvement, \$250,000 (Class 5)

To qualify for Level A based on severe renal involvement, you must submit the following:

The results of a urine collection test called a “24 hour urine creatinine clearance test”.

The results must show the creatinine clearance rate is less than 50% than would be normal for the same age and gender.

Your age at the time of the test is used to evaluate and compare it to the norm of the same age and gender.

Your medical records must reflect a chronic renal dysfunction.

NOTE: Kidney transplant or dialysis treatment will be credited for Level A unless the condition is related to a condition other than SLE.

Disease Option 2 SLE

Level B – Glomerulonephritis (\$200,000)

Glomerulonephritis is the inflammation of the glomerulus, which is the tiny ball-shaped structure of the kidney composed of capillary blood vessels actively involved in the filtration of the blood to form urine. (1)

To qualify, your records must reflect all of the following:

1. The symptom of Renal Disorder must be credited in the disease portion of the claim; **and**
2. All medical records that establish the diagnosis and treatment of lupus glomerulonephritis must be submitted, which may include:
 - Immunological studies that indicate lupus glomerulonephritis.
 - Kidney biopsy that indicates lupus glomerulonephritis.

(1) Source: Website: www.MedicineNet.com

Disease Option 2 SLE Level B – Seizures (\$200,000)

Seizures are episodes of uncontrolled electrical activity in the brain. These abnormal electrical disturbances may lead to involuntary jerking, spasms, or rhythmic contraction and relaxation of certain muscle groups. (1)

To qualify, your records must reflect all of the following:

1. The symptom of Neurologic Disorder must be credited in the disease portion of the claim; **and**
2. All medical records that establish the diagnosis and treatment of Seizures must be submitted, which may include:
 - Abnormal EEGs
 - Abnormal CT scans
 - Office notes and hospital records that reflect the seizures.

(1) Source: Website: www.MedicineNet.com

Disease Option 2 SLE Level B – Psychosis (\$200,000)

Lupus Psychosis is a serious mental disorder featuring defective thought processes, frequently with delusions or hallucinations. (1)

To qualify, your records must reflect all of the following:

1. The physician treating the claimant for psychosis must relate it to SLE; **and**
2. All medical records that establish the diagnosis and treatment of Lupus Psychosis must be submitted, which may include:
 - Abnormal EEGs, abnormal SPECT or PET scans
 - Abnormal neuro-psychological testing
 - Office records that reflect the clinical symptoms of dementia, delirium, disordered and bizarre thinking, delusions and hallucinations.

(1) Source: Website: www.MedicineNet.com

Disease Option 2 SLE Level B – Myocarditis (\$200,000)

Myocarditis is the inflammation of the heart muscle. The most frequent symptom of myocarditis is pain in the chest. When myocarditis is more serious, it leads to weakening of the heart muscle. Myocarditis can then cause heart failure (with symptoms of shortness of breath, fatigue, fluid accumulation in the lungs, etc.) as well as heart rhythm irregularities from inflammation and/or scarring of the electrical system of the heart. (1)

To qualify, your records must reflect all of the following:

1. The symptom of Serositis Disorder-Pericarditis must be credited in the disease portion of the claim; **and**
2. All medical records that establish the diagnosis and treatment of Myocarditis must be submitted, which may include:
 - EKGs that show ST wave and conduction abnormalities, and irregular heart beats
 - Office records that reflect the clinical symptoms of cardiomegaly (enlarged heart), resting tachycardia, congestive heart failure
 - Records reflecting positive RNP antibodies.

(1) Source: Website: www.MedicineNet.com

Disease Option 2 SLE Level B – Pneumonitis (\$200,000)

Pneumonitis is inflammation of the lungs. Acute Lupus Pneumonitis is characterized by fever, cough, sometimes hemoptysis (blood in sputum), pleurisy, difficulty breathing and/or shortness of breath. Chronic Lupus Pneumonitis may show abnormalities in lung tests.

To qualify, your records must reflect all of the following:

1. The symptom of Serositis Disorder-Pleurisy must be credited in the disease portion of the claim; **and**
2. All medical records that establish the diagnosis and treatment of Pneumonitis must be submitted, which may include:
 - Abnormal chest x-rays that show diffuse interstitial infiltrates
 - Abnormal pulmonary function tests that show a restrictive pattern
 - Office records that reflect the clinical symptoms of respiratory difficulty, such as shortness or difficulty breathing, bloody productive cough
 - Lung biopsy that confirms Lupus Pneumonitis
 - Bronchoalveolar lavage (tube inserted into the bronchial tree of the lungs) that shows greater than 10% neutrophils.

Disease Option 2 SLE Level B - Thrombocytopenic Purpura (\$200,000)

Thrombocytopenic Purpura is characterized by the destruction of platelets in the blood. Thrombocytopenia refers to a decrease in platelets (also known as thrombocytes). Purpura pertains to the visible hallmarks: purplish areas in the skin and mucous membranes (such as the mouth lining) where bleeding has occurred as a result of decreased platelets.

To qualify, your records must reflect all of the following:

1. The symptom of Hematologic Disorder-Thrombocytopenia must be credited in the disease portion of the claim; **and**
2. All medical records that establish the diagnosis and treatment of Thrombocytopenic Purpura must be submitted, including:
 - Laboratory reports showing platelet counts fewer than 20,000 cells
 - Office records that reflect the clinical symptoms of small hemorrhages in the skin such as bruising and purplish mucous membranes.

(1) Source: Website: www.MedicineNet.com

Disease Option 2 SLE

Level B - Hemolytic Anemia (\$200,000)

Hemolytic anemia is characterized by the decrease in red blood cells. It results from the abnormal destruction or breakdown of red blood cells.

To qualify, your records must reflect all of the following:

1. The symptom of Hematologic Disorder-Hemolytic Anemia with reticulocytosis must be credited in the disease portion of the claim; **and**
2. A laboratory that reflects a hemoglobin (Hgb) of 10 grams or less; **and**
3. Medical records that establish the diagnosis and treatment of Hemolytic Anemia must be submitted.

(1) Source: Website: www.MedicineNet.com

Disease Option 2 SLE

Level B - Severe Granulocytopenia (\$200,000)

Granulocytopenia is a marked decrease in the number of granulocytes. Granulocytes are a type of white blood cell filled with microscopic granules that are little sacs containing enzymes that digest microorganisms.

To qualify, your records must reflect all of the following:

1. The symptom of Hematologic Disorder- Leukopenia must be credited in the disease portion of the claim; and
2. A laboratory that reflects a white blood cell count (WBC) of less than 2,000 mm³ or 2.0; and
3. Medical records that establish the diagnosis and treatment of Granulocytopenia must be submitted.

(1) Source: Website: www.MedicineNet.com

Disease Option 2 SLE Level B - Mesenteric Vasculitis (\$200,000)

Mesenteric Vasculitis is inflammation of the vessels pertaining to the mesentery (a membranous fold attaching various organs to the abdominal body wall).

To qualify, your records must reflect all of the following:

1. The physician treating the claimant for mesenteric vasculitis must relate it to SLE; **and**
2. All medical records that establish the diagnosis and treatment of Mesenteric Vasculitis must be submitted.

Disease Option 2 SLE

Level B - unacceptable proof

Common reasons why claimants receive a compensation deficiency notice about their Level B condition:

- ✘ The physician's records do not contain a diagnosis or supporting treatment records to establish one of the Level B conditions.
- ✘ The condition was directly related to another cause other than the diagnosis of SLE. For example, Pneumonitis as a result of an infection, or thrombocytopenia as a result of taking a certain type of medication.
- ✘ The corresponding symptom was not credited in the disease review.
- ✘ The condition existed before the date you received your first breast implant.

Disease Option 2 SLE Level C – Default (\$150,000)

Level C is the default compensation level for any Claimant who has met all of the general and symptom requirements in the disease review for SLE Option 2.

If the claimant does not qualify for Level A or B, this level will be approved assuming all of the disease criteria are met.

SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) CLAIMS

DISEASE OPTION 1
INFORMATION

Systemic Lupus Erythematosus (SLE) Disease Option 1 Requirements

To submit a claim for SLE in Disease Option 1, you must document and submit **ALL** of the following documents:

- ❑ An evaluation by a Qualified Medical Doctor (QMD) (see page 85);

or

- ❑ Medical records supporting **THREE** (3) of the symptoms of SLE (see pages 86-87);

AND

- ❑ Documentation of the disability/severity level of the disease (see pages 94-104).

Acceptable Qualified Medical Doctors for Disease Option 1 SLE

One way to qualify for Disease Option 1 SLE is to submit a statement or Diagnosis from a Qualified Medical Doctor (QMD). A QMD is a physician who writes a letter for purposes of the settlement and is/or became board certified in one or more of the following specialties before (s)he wrote the letter:

1. Internal Medicine; or
2. Rheumatology; or
3. Allergy/Immunology; or
4. Doctor of Osteopathy with similar specialty certifications; or
5. Foreign doctor with equivalent specialty certification.

A physician with a status of “Board Eligible” does not qualify as a QMD. A physician can be Board Certified in more than one of these specialties. A QMD can also be your treating physician.

NOTE: For Disease Option 2 SLE claims only a diagnosis of a Board Certified Rheumatologist is accepted. For Disease Option 1 SLE claims (which offers less compensation), you can submit the medical records from any of the Board Certified Specialists listed above that document three of the symptoms listed on page 86.

Eligible symptoms for Disease Option 1 SLE

SLE in Option 1– requires documentation of any THREE (3) of the following symptoms:

- a. Malar Rash (see pages 13-16)
- b. Discoid Rash (see pages 17-20)
- c. Photosensitivity (see pages 21-23)
- d. Oral Ulcers (see pages 24-26)
- e. Arthritis (see pages 27-29)
- f. Serositis (see pages 30-34)
- g. Renal Disorder (see pages 35-37)
- h. Neurologic Disorder (see pages 38-42)
- i. Hematologic Disorder (see pages 43-52)
- j. Immunologic Disorder (see pages 53-54)
- k. Positive ANA (see pages 55-58)

The symptoms are the same symptoms listed for Disease Option 2 SLE. For more information on how to meet the criteria for these symptoms, please refer to the pages noted beside each symptom listed above.

NOTE: You do not need to submit the underlying office notes of the examinations, laboratory tests, skin biopsy report or EKG report or any other diagnostic test if the test results are adequately described in the QMD letter. However, it is best to submit the actual reports, because a QMD seldom writes all of the required elements of a report in his/her letter.

Deficiencies for SLE Disease Option 1

Common reasons why claimants receive a deficiency notice for Disease Option 1 SLE:

- The file does not contain at least 3 symptoms of SLE.
- The symptoms are related to other medical conditions.
- There is insufficient information to credit the SLE symptom.
- If you are relying on a QMD statement, the physician must be board certified in one of the specialties listed on page 85. If (s)he is not and your medical records do not support three eligible symptoms, this will result in a deficiency.

Disease Option 1 SLE – Pre-existing Statement

If you were diagnosed with SLE before the date you received your first breast implant, you can still qualify for Disease Option 1 SLE if your SLE increased in severity after your implantation.

The amount of compensation in this instance would be calculated by looking at the difference in severity of the disease before you were implanted and post-implantation.

SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) CLAIMS

DISEASE OPTION 1
Compensation



Compensation Levels for Disease Option 1 SLE

- **Severity or Disability Level A** - \$50,000 – There are three different ways that you may qualify for a Level A payment in Disease Option 1 SLE: Death (see page 94), or Total Disability (see pages 96-101) or severe renal involvement manifested by a decrease in glomerular filtration rates (see page 95).
- **Severity Level B** - \$20,000 – SLE with major organ involvement with one or more of the following: Glomerulonephritis, Central Nervous Involvement (i.e. seizures, or lupus psychosis), Myocarditis, Pneumonitis, Thrombocytopenia Purpura, Hemolytic Anemia (marked), Severe Granulocytopenia, Mesenteric Vasculitis (see page 102).
- **Severity Level C** - \$10,000 - Non-major organ involvement requiring regular medical attention, including doctor visits and regular prescription medications (see page 103).
- **Severity Level D** - \$10,000 – Non-major organ involvement requiring little or no treatment (see page 104).

The compensation amounts for approved SLE and ACTD claims in Disease Option 1 are the same, regardless of what Level of severity or disability that you are approved for. There are important proof differences however between disability proof for Option 1 SLE (which is based on the severity of the symptoms, total disability, or death) and ACTD (which is based primarily on your level of disability, or death). If you do not qualify for SLE and the claim is evaluated for ACTD, you will need to submit documents regarding the level of your disability consistent with the disability criteria for ACTD.

Disease Option 1 SLE Level A – Death, \$50,000

Severity levels for SLE are compensation levels based on the extent of organ involvement. If the physician's statement or the claimant's medical records reflect the required extent of organ involvement, a severity level can be approved without a separate letter from a physician.

Disease Option 1 SLE – Premium Payments

If Premium Payments are approved by the District Court, approved Option 1 SLE claimants could receive an additional payment of up to 20% of their approved compensation amount.

Level A – Premium Payment of up to \$10,000 (Class 5)

Level B – Premium Payment of up to \$ 4,000 (Class 5)

Level C or D – Premium Payment of up to \$2,000
(Class 5)

Accepting a Disease Option 1 SLE Payment

Once you accept payment for a Disease Option 1 SLE claim, you cannot later apply for Disease Option 2 SLE, even if you later qualify. You can, however, apply for an Increased Severity Payment in Disease Option 1 if your condition later qualifies for Severity or Disability Level A. Increased Severity Payments are treated the same as Premium Payments in the Plan in terms of when they're authorized to be paid and are subject to an overall cap for all claims that qualify for increased severity in Disease Option 1 of \$15 million NPV.

Disease Option 1 SLE

Level A – Death (\$50,000)

To qualify for Level A based on a claimant's death, you must submit ONE of the following:

- A death certificate that indicates the primary or secondary cause of death is related to Systemic Lupus Erythematosus or an approved SLE symptom; or
- An autopsy report that indicates the cause of death is related to SLE; or
- A letter from a QMD or the claimant's medical records that directly relate the primary or secondary cause of death to SLE or an approved SLE symptom.

Level A based on a claimant's death can be approved without a death certificate or autopsy report. The claimant's death cannot be caused by any other disease or condition.

Disease Option 1 SLE

Level A – Severe Renal Involvement (\$50,000)

To qualify for Disease Option 1 SLE, Level A, your records must reflect ongoing renal involvement with documentation of ONE of the following:

1. Abnormal 24 hour urine creatinine clearance test with proteinuria greater than 0.5 grams per day; or
2. Urinalysis with proteinuria greater than 3+; or
3. Cellular casts; or
4. Diagnosis of nephritic syndrome; or
5. Kidney transplant; or
6. Dialysis treatment.

Disease Option 1 SLE Level A – Total Disability (\$50,000)

The Claims Resolution Procedures document defines Disability A as: “Death or total disability resulting from the compensable condition. An individual will be considered totally disabled if she demonstrates a functional capacity adequate to consistently perform none or only a few of the usual duties or activities of vocation or self-care.”

The SF-DCT’s current standard for Disability Level A claims requires claimants to submit proof that they are disabled in both vocation and self-care. The CAC has a motion pending before the court on this issue. If you filed a claim for a Level A and did not qualify because of this issue, you may accept a lower payment for a Level B or C disability claim (if you qualify). If the Court rules in favor of the CAC, the SF-DCT will identify claims potentially affected by the ruling, re-review them and notify claimants accordingly.

Disease Option 1 SLE

Level A - Total Disability (\$50,000)

You can qualify for a Level A payment in Disease Option 1 SLE by documenting that you are totally disabled, as defined in the Plan. There are several ways the QMD or Treating Physician can assign a Level A total disability. Listed below are some acceptable examples of assignments for Level A disability provided that there is an adequate description of your limitations in performing both vocation and self-care, either in the QMD letter or the medical records:

- The physician can describe your limitations in performing both your vocation and self-care activities; **or**
- The physician can simply state “Level A” disability and then describe the vocation and self-care limitations; **or**
- The physician can use other phrases such as “completely disabled” or “totally disabled” and then describe the vocation and self-care limitations.

Note: If you submit several disability letters with different dates, and only the most current letter states that you are now totally disabled, then you must submit current medical records from a new examination that supports the Level A disability. The new disability rank cannot be based solely on a phone call the doctor had with you or a review of a questionnaire that you completed.

Note: If you are relying solely on a QMD letter, the SF-DCT may, in limited circumstances described in Section 5.04 of the Settlement Facility and Fund Distribution Agreement, request additional medical records to support a claim.

Disease Option 1 SLE

Level A Total Disability: Vocation

To be considered totally disabled in your vocation, you must show that you are unable to do one of the following because of the limitations from your credited symptom(s):

- If you work outside the home, you must show that you are unable to work in your primary occupation, or
- If you do not work outside the home and were attending school, you must show that you are either unable to go to school, or
- If you were doing volunteer work, you must show that you are unable to do volunteer work.
- If you are a homemaker and this is your primary occupation, you must show that you are unable to perform your homemaking duties.

NOTE: If the physician adequately describes your limitations in performing your vocation and self-care, but indicates that you are able to perform your homemaking duties, the SF-DC cannot approve your claim for Level A total disability. Your ability to adequately and regularly perform your homemaking activities conflicts with the description of your inability to perform your vocation and self-care.

Example: Ms. Jones is unable to work due to chronic fatigue, however, she is able to perform most of her household duties. Due to her severe joint pain, she requires a home health aide at least 5 days a week to assist with dressing and grooming.

Examples of homemaking activities are cooking, washing dishes, cleaning, sweeping or vacuuming, washing windows, dusting, mopping, laundry, changing bed linens and/or shopping.

Disease Option 1 SLE

Level A Total Disability: Self-care

To be approved for limitations in performing your self-care activities, your medical records -- when read together to reflect an overall description of your limitations -- must show that you are not able to perform two self-care activities listed below either by yourself or without assistance from another person or an assistive device.

1. Bathing
2. Dressing
3. Grooming
4. Feeding
5. Toileting

The need for assistance "means" a claimant is unable to perform an activity alone and requires help from others or a special device to complete a specific activity due to a credited symptom. The records or the physician's statement must indicate the need for assistance and taken as a whole must demonstrate that these self-care activities cannot be done without assistance or an assistive device. Assistance must be needed when performing the primary act of the self-care activity.

Disease Option 1

Level A – Total Disability (\$50,000)

Disability A Example:

Medical records from 1974 reflect that Ms. Jones, a homemaker, had severe arthritis in her hands. Records dated from 1995 through 2000 reflect that she required assistance from friends and family members to cook, clean, vacuum and grocery shop due to the pain of her hand arthritis (vocational disability from her homemaking activities). In addition, her daughter must assist her with dressing and undressing and must help her with toileting and getting on and off the toilet (self-care disability).

The SF-DCT will review the totality of the file in reviewing total disability claims.

Disease Option 1 SLE

Level A Total Disability: Vocation – unacceptable proof

The following are unacceptable examples of total disability:

- Your records show that you continue to work in your job/employment.
- “Permanently disabled.” This is not the same as totally disabled.
- Your records show that your primary vocation is affected or limited by an ineligible symptom or condition, for example: work injury, car accident, heart attack, non-SLE symptom, such as fatigue or myalgias.
- The treating doctor or QMD letter states that you are totally disabled, but your medical records dated within the same time frame indicate that you are very active exercising.
- The QMD or treating doctor bases your total disability on a pre-existing symptom or condition.
- The treating doctor or QMD bases your Level A total disability rank on symptoms that were not eligible or approved. For example, the QMD states that you are unable to work because of arthritis, but you were not credited with the symptom of arthritis.
- If your file mentions homemaking then in order to qualify the records must reflect that you have difficulty performing this activity.

Disease Option 1 SLE Level B – Organ Involvement (\$20,000)

The severity level requirements for Level B are the same in both Disease Options 1 and 2 SLE. (See pages 72 -81 for information on acceptable ways to document organ involvement).

Disease Option 1 Level B has one additional way to document organ involvement: Central Nervous System Involvement (CNS). In Disease Option 1, this condition can involve any lupus CNS condition of the brain, spinal cord, nerves, and senses, and not just seizures or lupus psychosis.

Disease Option 1 Level C – Non-major Organ Involvement (\$10,000)

Disease Option 1 Level C is defined as non-major organ involvement. A Claimant will be approved at this level if her medical records support regular medical attention, including doctor visits and prescription medications.

Disease Option 1 Level D - Mild Lupus (\$10,000)

Disease Option 1 SLE Level D is the “default level,” i.e., if a claimant has at least three qualifying symptoms of SLE but does not have major organ involvement and has little or no ongoing treatment, then the claim will be approved at Level D.

Listed below are the differences between Disease Option 1 and 2 claims for SLE

DISEASE OPTION 2	DISEASE OPTION 1
You must be examined by a Board Certified Rheumatologist (BCR).	You can rely on the evaluation by a “Qualified Medical Doctor,” treating doctor, or on a review of your medical records by the SFDCT.
You must have a diagnosis of SLE by the BCR who examined you. To qualify for Level C compensation, you must submit a statement by your BCR that you do not have “Mild Lupus” as that term is defined in the Plan.	You can qualify if you do not have a diagnosis of SLE if you have at least three approved symptoms. You do not need a statement regarding whether you have “Mild Lupus.”
You must submit the physician’s office notes, the laboratory reports, chest x-rays, EKG reports and skin biopsy reports that support your approved symptoms.	You must submit the medical records or a QMD evaluation that support your symptoms. You are not required to submit the laboratory report, chest x-ray, EKG report or skin biopsy report if these symptoms are adequately documented in the QMD letter or medical records.
Your symptoms must have occurred within a single 24 month within 5 years of submitting your claim	There is no 24 month/5 year time frame requirement in Option I.
Pre-existing SLE symptoms <u>will not</u> be credited as eligible symptoms. You must submit a letter or statement from your BCR stating that none of your symptoms existed prior to the date of your first breast implantation.	Pre-existing SLE symptoms can be credited as eligible symptoms; however, the amount of compensation will depend on whether the severity or disability of the disease became worse after implantation.