

SF-DCT INFORMATION FOR SCLERODERMA (SS) CLAIMS

OPTIONS 1 & 2

Scleroderma (SS)

Scleroderma (skler-a-DER-ma) – Scleroderma is a chronic and progressive disease that causes inflammation and thickening of the skin and the formation of scar tissue in organs. Scleroderma is also referred to as Systemic Sclerosis (abbreviated as “SS”).

The term scleroderma encompasses two groups: localized scleroderma or morphea, where problems are confined to the skin, and systemic or diffuse sclerosis where internal organs (esophagus, kidneys, lungs, bowels) and blood vessels are involved as well as the skin.

Localized Scleroderma vs. Systemic Sclerosis

Localized Scleroderma (Morphea) is compensated only in Disease Option 1. It is not eligible for compensation in Disease Option 2.

Systemic Sclerosis is compensated in Disease Option 1 or Disease Option 2, depending on whether you have a diagnosis of Scleroderma from a Board Certified Rheumatologist and on the severity of the symptoms that you document. The Settlement Facility will review your claim for Scleroderma first to see if it meets the criteria for compensation in Disease Option 2. If there are any deficiencies in the claim, then the Settlement Facility will review your claim to determine if you qualify for Disease Option 1 Scleroderma or, if applicable, for Atypical Connective Tissue Disease (ACTD) in Disease Option 1. A chart summarizing key differences between Disease Option 1 and 2 Scleroderma claims is on page 72.

SCLERODERDERMA CLAIMS

DISEASE OPTION 2
INFORMATION

Scleroderma (SS) Disease Option 2 Requirements

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

- ❑ 1) A diagnosis of Systemic Sclerosis / Scleroderma (SS) (see pages 6, 7, and 8); **and**
- ❑ 2) made by a Board Certified Rheumatologist (BCR) (see pages 6, 7, and 8); **and**
- ❑ 3) based upon personal examination by the BCR. (see pages 9 and 10); **and**

In addition, you must submit the following documents:

- ❑ 4) A statement from the BCR that you do not have only localized scleroderma (morphea) (see page 11); **and**
- ❑ 5) All medical records (including lab reports) that document your qualifying symptoms and the diagnosis of Scleroderma; **and**
- ❑ 6) All your qualifying symptoms must have occurred within a 24 month period (see pages 22 and 25); **and**
- ❑ 7) 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 23-25 for additional information.); **and**
- ❑ 8) A statement from the BCR that you did not have any of the qualifying symptoms of Scleroderma before you received your first breast implant. (see page 26-28)

1a) You must have a diagnosis of Scleroderma from a BCR

The following are acceptable ways for a BCR to document a diagnosis:

- Mrs. Jones has Scleroderma (or Systemic Sclerosis).
- Mrs. Jones has the symptoms of Scleroderma, and therefore, I conclude that she has Scleroderma (or Systemic Sclerosis).
- Mrs. Jones satisfies the symptom criteria for a diagnosis of Scleroderma (or Systemic Sclerosis).
- I have treated Mrs. Jones for Scleroderma since 1989.
- A notation in the medical record stating, “Scleroderma” or “Systemic Sclerosis” or an abbreviation for Scleroderma.

1b) Common problems with crediting a diagnosis of Scleroderma

Common reasons why claimants receive a deficiency about the diagnosis of Scleroderma 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 Scleroderma. 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 "Scleroderma-type" or "Scleroderma-like" disease.
- The diagnosis is written as "possible," "probable" or "most likely Scleroderma." It must affirmatively state that you have Scleroderma.
- A diagnosis of Scleroderma 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 Scleroderma 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 Scleroderma, 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

To qualify for Disease Option 2 scleroderma, you must have been examined by a Board Certified Rheumatologist. 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 will 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 symptoms during one exam. If (s)he has reviewed your medical records and concludes that you have Scleroderma based on the exam, then the Settlement Facility will credit the exam.

4) You must submit a statement that affirms that you do not have only Localized Scleroderma (the “Exclusion Statement”)

If you have only Localized Scleroderma, this is not eligible for compensation in Disease Option 2. You may have an area of localized scleroderma and still be eligible for Disease Option 2 if you also have systemic scleroderma.

If you fit the example in #1 below, then you must submit a written statement from your Board Certified Rheumatologist confirming that your Scleroderma is systemic, and not just localized (the “Exclusion Statement”).

1. EXCLUSION STATEMENT IS REQUIRED:

- If there is a diagnosis of Systemic or Diffuse Sclerosis and you qualify for Scleroderma relying only on the symptoms of Sclerodactyly and Digital Pitting, then your Board Certified Rheumatologist must state in a letter that you do not have Localized Scleroderma (the Exclusion Statement).

2. EXCLUSION STATEMENT IS NOT REQUIRED:

- If there is a diagnosis of Systemic or Diffuse Sclerosis and the medical records document symptoms sufficient to qualify you for Scleroderma Level A or Level B in the Plan, then it will be inferred that you do not have Localized Scleroderma and you do not need to submit an “Exclusion Statement.”
- If there is a diagnosis of Systemic or Diffuse Sclerosis and you qualify for Scleroderma based on the symptom of Proximal Scleroderma or Bibasilar Pulmonary Fibrosis, then it will be inferred that you do not have Localized Scleroderma and you do not need to submit an “Exclusion Statement.”

5) What are the symptoms of Scleroderma in Disease Option 2?

The Dow Corning Plan follows the American College of Rheumatology criteria for the classification of Systemic Sclerosis. To qualify, your medical records must document that you have ONE Major Criterion or TWO Minor Criteria:

A. Major Criterion:

Proximal scleroderma – symmetric thickening, tightening, and induration of the skin of the fingers and the skin proximal to the metacarpophalangeal or metatarsophalangeal joints. The changes may affect the entire extremity, face, neck and trunk (thorax and abdomen) (see pages 13, 14, and 15); or

B. Minor Criteria:

1. Sclerodactyly – includes the above major criterion characteristics (skin changes) but is limited to only the fingers (see pages 16 and 17); and/or

2. Digital pitting scars or a loss of substance from the finger pad: as a result of ischemia, depressed areas of the finger tips or a loss of digital pad tissue occurs (see pages 18 and 19); and/or

3. Bibasilar pulmonary fibrosis includes a bilateral reticular pattern of linear or lineonodular densities most pronounced in basilar portions of the lungs on standard chest roentgenogram. These densities may assume the appearance of diffuse mottling or “honeycomb lung” and are not attributable to primary lung disease (see pages 20 and 21).

5A) MAJOR CRITERION: PROXIMAL SCLERODERMA and how it is credited

To credit the symptom of Proximal Scleroderma, the office notes of the exam must show ONE of the following:

- Thickening and tightening of the skin nearest to the Metacarpophalangeal (MCP) joints (This is the area between the knuckles and the wrist area. Carp refers to the eight bones of the wrist); or
- Thickening and tightening of the skin nearest to the Metatarsophalangeal (MTP) joints (This is the area between the toes and the forefoot. Tarso refers to the toe joints); or
- Thickening and tightening of the skin on the extremities, face, neck, and/or trunk (chest, back, abdomen or flanks).

5A) MAJOR CRITERION: PROXIMAL SCLERODERMA and how it is credited

Examples of acceptable ways that a Board Certified Rheumatologist might document Proximal Scleroderma:

- √ “There is thickening induration of hands and wrists.”
- √ “Sclerodermatous skin over feet and hands.”
- √ “There is an absence of normal skin fold areas around mouth ... tightness of skin.”
- √ “The patient had radial furrowing” or “the patient had grooves radiating out from around the mouth and lips.”
- √ “I am unable to lift up or pinch the skin on the back because of tethering.”
- √ “The patient’s skin is hidebound” or “the patient has hardening and thickening of the skin with loss of elasticity.”
- √ A Rodnan total skin score (TSS) of 2 or higher. (A Rodnan test is a clinical palpitation method used for monitoring skin change and/or progression of skin thickening: 0 – normal, 1 – mild, 2 – moderate, 3 – severe, and 4 is extreme skin thickening).

5A) MAJOR CRITERION: PROXIMAL SCLERODERMA- unacceptable proof

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

- The medical records reflect that the claimant has multiple areas of induration, discrete lesions, or skin thickening but does not state the body parts or areas that are affected.
- The medical records reflect that the claimant has skin thickening or tightening but it is found only on the fingers or toes, and not on the area above the knuckles and below the wrist (proximal to the MCP and MTP joints). This may, however, be sufficient to credit you with the symptom of Sclerodactyly.
- The Board Certified Rheumatologist directly relates that the skin thickening is caused by other diseases such as eczema, porphyria cutanea tarda, scar tissue, or keloid scars.
- Your medical records show that you were diagnosed with Proximal Scleroderma before you received your first breast implant.

5B) MINOR CRITERION: SCLERODACTYLY and how it is credited

Sclerodactyly (skler-o-DAK-til-e) is the localized thickening and tightening of the skin of the fingers or toes on one or more hands or feet. The skin becomes tight, thin and shiny and the fingers and toes may not bend or may become fixed in a flexed or less functional position. To credit Sclerodactyly as an eligible symptom in the Plan, you must document the thickening and tightening in your fingers.

Examples of acceptable ways that a Board Certified Rheumatologist might document Sclerodactyly:

- The BCR states that patient has sclerodactyly; or
- The BCR states that the patient has skin thickening limited to the fingers; or
- The BCR states that the patient has skin tightening limited to the fingers; or
- The BCR states that the patient has Induration (localized hardening) limited to the fingers.
- The BCR states that “the skin of the fingers have very minimal thickening.”
- The BCR states that the patient’s “fingers have multiple areas of induration.”
- The BCR states that there is “very questionable slight thickening of the skin at the DIPs.”
- The BCR states that there is “thickening of the fingers.”

5B) MINOR CRITERION: SCLERODACTYLY - unacceptable proof

Examples of common reasons why claimants receive a deficiency notice about the symptom of Sclerodactyly:

- The BCR states that the patient's fingers are "sclerodactyly-like." To credit the symptom, the BCR must state that the patient has sclerodactyly.
- The BCR states that "It appears to be sclerodactyly." To credit the symptom, the BCR's statement must be more affirmative, i.e., "The patient has sclerodactyly."
- Your medical records show that you had Sclerodactyly before you received your first breast implant.

5B) MINOR CRITERION: DIGITAL PITTING and how it is credited

Digital Pitting is a depressed area at the tip of a finger or loss of digital pad tissue as a result of ischemia (insufficient supply of blood and oxygen to a part of the body that may lead to cell death). To credit the symptom of Digital Pitting, the office notes of the exam must reflect **ONE** of the following descriptions of your finger tips:

- Loss of substance; and/or
- Depressed areas; and/or
- Necrosis; and/or
- Erosion; and/or
- Loss of digital pad tissue referring to the fingers; and/or
- Ischemic ulcer along digits; and/or
- Digital pitting scars.

A diagnosis of "digital pitting" alone without any description is acceptable to credit the symptom.

5B) MINOR CRITERION: DIGITAL PITTING - unacceptable proof

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

- The BCR states that the digital scars and loss of finger pad substance are directly related to Raynaud's Phenomenon and not to the diagnosis of Scleroderma.
- Your medical records show that you had Digital Pitting before you received your first breast implant.

5C) MINOR CRITERION: BIBASILAR PULMONARY FIBROSIS and how it is credited

Bibasilar Pulmonary Fibrosis is a bilateral reticular pattern of linear or lineonodular densities that are most pronounced in basilar portions of the lungs. It may assume the appearance of diffuse mottling or “honeycomb lung” and should not be attributable to primary lung disease.

To credit the symptom of **Bibasilar Pulmonary Fibrosis**, you must submit the report of **ONE** of the following tests that show evidence of Bibasilar Pulmonary Fibrosis:

- A chest x-ray, **or**
- Computed Tomography (CT).

Note: SF-DCT **will** consider for possible approval any chest x-ray or CT reports that may not use the exact description of the lung changes noted in Annex-A (page 103), if it can be interpreted to be the same and there is a physician statement indicating that he/she considers the pulmonary changes to be pulmonary fibrosis.

Note: If the BCR performs a pulmonary x-ray in his office and (s)he documents that the patient has Bibasilar Pulmonary Fibrosis in his/her office notes, but there is no separate x-ray report, the SF-DCT will take this under consideration, if the Claimant’s records support pulmonary illness related to Scleroderma.

5C) MINOR CRITERION: BIBASILAR PULMONARY FIBROSIS - unacceptable proof

Common reasons why claimants receive a deficiency notice about the symptom of Bibasilar Pulmonary Fibrosis:

- The x-ray or CT scan report does not contain an acceptable description of bibasilar pulmonary fibrosis.
- The x-ray or CT scan report does not contain a sufficient description that both lung bases are affected.
- The BCR directly relates the pulmonary changes to another cause or lung condition.
- Your medical records contain a diagnosis of Bibasilar Pulmonary Fibrosis but you did not submit the x-ray or CT scan report.
- Your medical records show that you were diagnosed with Bibasilar Pulmonary Fibrosis before you received your first breast implant.

6) 24 Month Rule for Disease Option 2 Claims

To qualify for Disease Option 2 Scleroderma, 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.

7) 5 Year Filing Deadline for Disease Option 2 Claims

To qualify for Disease Option 2 Scleroderma, 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.

7) 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.

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.

8) Pre-existing Symptoms for Disease Option 2 Scleroderma

To meet the Plan's requirements, your Board Certified Rheumatologist 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 to document that you did not have pre-existing symptoms:

- Based on history, she did not have any symptoms of Scleroderma before she received her first breast implant; or
- The patient first experienced symptoms of Scleroderma 2 years after she received her first breast implant; or
- The patient did not have any symptoms of Scleroderma until after she received her first breast implant; or
- The patient's symptoms started 3 years after she received her first breast implant.

8) Pre-existing Symptoms for a Disease Option 2 Scleroderma claim

If you were diagnosed with Systemic Sclerosis and all your qualifying symptoms were documented before you received your first breast implant, then you are not eligible for compensation in Disease Option 2. You may, however, still be eligible for compensation in Disease Option 1 (see pages 40-69 for more information).

If your medical records show that you had any documented symptoms / diagnosis of any symptoms of Scleroderma before you received your first breast implant, then we cannot credit that symptom to qualify you for Scleroderma in Disease Option 2. You may still qualify for Scleroderma if you can document other symptoms that qualify you.

8) The BCR must document that you did not have the symptoms of Scleroderma before you received your first breast implant

The following statement about a claimant's pre-existing symptoms is unacceptable:

- The patient did not have Scleroderma before she received her first breast implant.

This is unacceptable. The Board Certified Rheumatologist must document that you did not have the qualifying symptom(s) of Scleroderma before you received your first breast implant.

SCLERODERMA CLAIMS

DISEASE OPTION 2
COMPENSATION

Compensation for Disease Option 2

Scleroderma

Compensation for Scleroderma 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 SS, 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 32 and 33 for more information).

LEVEL B – Base Payment of \$200,000 (Class 5) - Clinically significant cardio-pulmonary manifestations of scleroderma or proximal scleroderma on the trunk (thorax and abdomen) (see pages 34-38 for more information).

LEVEL C – Base Payment of \$150,000 (Class 5) - A diagnosis of SS as required in the Plan that does not involve the findings in Levels A or B above (see page 39 for more information).

Premium Payments for Disease Option 2 Scleroderma

If Premium Payments are approved by the District Court, approved SS 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 Scleroderma

Level A - Death related to SS, \$250,000 (Class 5)

To qualify for Level A based on death resulting from SS, 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 SS or one of the approved SS symptoms; **or**
- An autopsy report that indicates the cause of death is related to SS or one of the approved SS 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 SS or one of the approved SS 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 Scleroderma Level A - Severe Chronic Renal Involvement, \$250,000 (Class 5)

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.

To qualify for Level A based on severe chronic renal involvement, the Settlement Facility requires you to submit 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% that 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.

Disease Option 2 Scleroderma Level B - Cardiopulmonary manifestations, \$200,000 (Class 5)

You may qualify for cardiopulmonary manifestations if your medical records reflect **ONE** of the following:

- **Interstitial Fibrosis** – documented by physical findings and an abnormal chest x-ray or chest CT scan; **or**
- **Pulmonary Hypertension** – documented by physical findings and either a 2D-echo doppler or angiography with hemodynamic measurements showing pulmonary artery pressures of greater than 25 TORR.

Disease Option 2 Scleroderma

Level B - Interstitial Fibrosis

A finding of Interstitial Fibrosis must be based on physical exam that includes early and late findings of the condition.

Early Findings:

Office notes with breathlessness, non-productive cough, diffuse rales and rhonchi (coarse rattling sound).

Later Findings:

Office notes or lab reports that show signs of right sided heart failure, pulmonary hypertension, elevated ESR, elevated serum immunoglobulin, depressed lung volume and diffusion capacity, resting hypoxia with mild hypocapnia, and/or exercise induced impairment of gas exchange.

Disease Option 2 Scleroderma

Level B - Interstitial Fibrosis

In addition to the physical findings of Interstitial Fibrosis, there must be abnormalities on a chest x-ray or chest CT scan that include ONE of the following:

- x-ray showing diffuse, hazy, ground-glass appearance or reticulonodular pattern; or
- x-ray showing classic honey-comb lung; or
- chest CT showing sub-pleural reticular opacities and that the distribution of fibrosis is peripheral. Cystic air space (honeycomb cysts) are frequently found.

Disease Option 2 Scleroderma Level B – Pulmonary Hypertension

To credit Pulmonary Hypertension, you must submit the results of a 2-D-echo Doppler or angiography with hemodynamic measurements showing pulmonary artery pressures greater than 25 TORR.

In addition, a finding of Pulmonary Hypertension must be based on other physical findings which may include the following:

- Office notes with findings of fatigue, chest discomfort, tachypnea, dyspnea, (particularly in exercise); or
- Abnormal chest x-ray showing enlarged right heart border or EKG showing right ventricular hypertrophy; or
- Cor pulmonale – this is a condition in which there is decreased cardiac output with exercise and ECG shows right ventricular hypertrophy. Chest pain is common; may have pulmonic valve murmur.

**Disease Option 2 Scleroderma
Level B - Proximal Scleroderma on the Trunk,
\$200,000 (Class 5)**

To credit Proximal Scleroderma on the trunk (thorax and abdomen), the medical records must document the Proximal Scleroderma is present on both the thorax and abdomen.

Disease Option 2 Scleroderma Level C - \$150,000 (Class 5)

Claimants who have a diagnosis of Scleroderma consistent with the criteria in the Plan and meet all other requirements but who do not qualify for Levels A or B will be compensated at Level C, \$150,000 (Class 5).

SF-DCT INFORMATION FOR SCLERODERMA (SS) CLAIMS

DISEASE OPTION 1 INFORMATION

How Scleroderma claims are reviewed:

Claims for Scleroderma are first reviewed under Disease Option 2 criteria. If the claim is deficient, the claim will also be reviewed to see if it qualifies for Disease Option 1 Scleroderma and, if applicable, for Atypical Connective Tissue Disease (ACTD), which is also a Disease Option 1 condition.

Scleroderma Disease Option 1 Requirements

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

- ❑ An evaluation by a Qualified Medical Doctor (QMD) (see page 43); **or** medical records supporting ONE (1) of the symptoms of Scleroderma (see page 44);

AND

- ❑ Documentation of the severity level of the disease (see pages 48, 51, 52-69).

Acceptable Qualified Medical Doctors for Scleroderma Disease Option 1

One way to qualify for Scleroderma Disease Option 1 is to submit a QMD statement or diagnosis. 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 Scleroderma claims only a diagnosis of a Board Certified Rheumatologist is accepted. For Disease Option 1 Scleroderma claims (which offers less compensation), you can submit the medical records from any of the Board Certified Specialists listed above that document one of the symptoms listed on page 44.”

Disease Option 1 Scleroderma and how it is credited

To qualify for Disease Option 1 Scleroderma, the QMD or medical records must document either:

- Skin thickening, a diagnosis of sclerodactyly or descriptions of skin thickening limited to the fingers or Localized scleroderma or Morphea (a patchy area of the skin that becomes hardened and slightly pigmented, might be whitish with a purple ring) or
- Sine scleroderma, which is the internal organ manifestations of the disease, such as vascular and serologic abnormalities, but without any detectable skin changes.

Deficiencies for Scleroderma Disease

Option 1

Common reasons why claimants receive a deficiency notice for Scleroderma, Option 1:

- The file does not contain any evidence of skin changes consistent with Scleroderma.
- Skin changes are related to other skin conditions (such as keloid scars) and are not Scleroderma.
- Skin Biopsy reports state a diagnosis of a condition other than Scleroderma.

Scleroderma-like disease

The Plan refers to "Scleroderma-like" disease or "atypical" presentations of scleroderma in Disease Option 1. To qualify for Scleroderma-like in Disease Option 1, you must document at least ONE symptom listed on page 44 and meet the Severity Level criteria."

SCLERODERMA (SS) CLAIMS

DISEASE OPTION 1
Compensation

What are the Levels of Compensation for Systemic Sclerosis or Scleroderma in Option 1?

- 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 Scleroderma: Death (see page 52), or Total Disability (see pages 53-58) or severe renal involvement manifested by a decrease in glomerular filtration rates (see page 59).
- Severity Level B - \$20,000 – Cardio-pulmonary involvement or diffuse (Type III) Scleroderma skin changes (see pages 60-63).
- Severity Level C - \$10,000 - Other, including CREST, limited or intermediate scleroderma (see pages 64-70).
- Severity Level D - \$10,000 – All cases other than those covered above, including localized scleroderma (see page 71).

The compensation amounts for approved Scleroderma 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 Scleroderma (which is based on the severity of the symptoms, totally disability, or death) and ACTD (which is based primarily on your level of disability, or death). If you do not qualify for Scleroderma 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.

Premium Payments for Disease Option 1 Scleroderma

If Premium Payments are approved by the District Court, approved Option 1 SS 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 Scleroderma Payment

Once you accept payment for a Disease Option 1 Scleroderma claim, you cannot later apply for Disease Option 2 Scleroderma, 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.

Definition of Severity Level Compensation for Scleroderma

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

Disease Option 1 Scleroderma

Level A – Death, \$50,000 (U.S.)

One way to qualify for Level A is based on a claimant's death. To do this, you must submit ONE of the following:

- A death certificate that indicates the primary or secondary cause of death is related to SS or one of the approved conditions; or
- An autopsy report that indicates the cause of death is related to SS; or
- A letter from a QMD or the claimant's medical records that directly relate the primary or secondary cause of death to SS or one of the approved SS 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.

Functional Disability Level A Claims

- 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 Scleroderma

Level A Total Disability: Vocation and Self-Care

The second way to qualify for a Level A payment in Disease Option 1 Scleroderma is to document 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 Scleroderma

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, then your file must reflect that you are having difficulty maintaining or keeping up activities around the house. Some of the activities of homemaking are cooking, washing dishes, cleaning, sweeping or vacuuming, washing windows, dusting, mopping, laundry, and/or shopping.

NOTE: You do not need to describe your homemaking limitations unless you are a homemaker. If your records or disability letter does mention homemaking activities (even if you document that you are totally disabled in your vocation and self-care), then the records must reflect that you have difficulty performing these activities in order for you to qualify.

Disease Option 1 Scleroderma

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.

Level A – Total Disability (100%), \$50,000 (U.S.)

Disability A Example:

Medical records from 1974 reflect that Ms. Jones, a homemaker, had severe contractures in her hands due to her Sclerodactyly (the skin tightening around the fingers and hand areas). 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 loss of use of her hands (vocational disability from her homemaking activities). In addition, because of the Sclerodactyly in her hands, her daughter must assist her with dressing and undressing and must help her with getting on and off the toilet (self-care disability).

The SF-DCT will review the totality of the file in reviewing total disability claims. Limitations in vocation and self-care for Scleroderma claims are different than vocational and self-care limitations for claimants with ACTD. Readers are cautioned that disability claims for ACTD will require additional and/or different factual information and/or more specificity to qualify for Level A total disability.

Disease Option 1 Scleroderma

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, etc.
- 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 dysphagia and severe heartburn but you were not credited with the symptom of dysphagia or severe heartburn (esophageal dysmotility).
- If your file mentions homemaking then in order to qualify the records must reflect that you have difficulty performing this activity.

Disease Option 1 Scleroderma Severity Level A - Severe Renal Involvement

The third way to qualify for a Level A payment in Disease Option 1 Scleroderma is if your medical records show severe renal involvement manifested by a decrease in glomerular filtration rates, as documented by:

- Abnormal 24 hour urine creatinine clearance test; or
- Lab report that shows fragmented red cells or urinalysis with elevated protein and red cells that is significant enough to support renal involvement.

Disease Option 1 Scleroderma Severity Level B - \$20,000 (Class 5)

To qualify for Disease Option 1 Scleroderma, Level B compensation, the medical records must document either:

- Cardio-pulmonary involvement (see pages 61 and 62); or
- Diffuse (Type III) Scleroderma skin changes (see page 63).

Disease Option 1 Scleroderma Severity Level B – Cardio-pulmonary Involvement

To qualify for Disease Option 1 Scleroderma, Severity Level B based on Cardio-pulmonary involvement, there must be involvement of either the heart or the lungs as documented in the medical records.

Examples of cardiac clinical symptoms that a physician must describe and relate to Scleroderma are:

- ventricular gallops
- sinus tachycardia
- signs and symptoms of congestive heart failure (CHF)
- pericardial friction rub which is observed on an ECHO as pericardial thickening or effusion
- EKG abnormalities (may include: at rest, atrial and ventricular arrhythmias and conduction disturbances; with ambulation, SVT & VT arrhythmias)
- pericarditis and cardiac tamponade

Disease Option 1 Scleroderma Severity Level B – Cardio-pulmonary Involvement

Examples of pulmonary clinical symptoms that a physician must describe and relate to Scleroderma are:

- dyspnea on exertion
- limited effort tolerance
- non-productive cough
- chest pain
- pleuritic symptoms
- inspiratory crackling rales
- pulmonary hypertension with exaggerated second heart sound
- right ventricular gallops
- murmurs of pulmonic and tricuspid insufficiency
- jugular venous distension
- hepatojugular reflux

Disease Option 1 Scleroderma Severity Level B -- Diffuse (Type III) Scleroderma skin changes

To credit Disease Option 1 Scleroderma, Severity Level B, you must have Scleroderma **skin changes on the trunk**, as well as more than one additional area of the body.

The distributions of the skin changes over the whole body and the rate of change may be variable from a few months to several years. These changes may occur in the upper arms, shoulders, anterior chest, back, abdomen and legs. In the late stages atrophy develops, leading to fragility and laxity of the skin (superficial dermis). Tethering to deeper tissue may be evident.

Disease Option 1 Scleroderma Severity Level C

To qualify for Level C Severity Level, the Claimant must have Sclerodactyly **and** two additional symptoms of CREST:

CREST stands for:

C ... Calcinosis (see page 65)

R ... Raynaud's Phenomenon (see page 66)

E ... Esophagus (see page 67)

S ... Sclerodactyly (see page 16, 17 and 68)

T ... Telangiectasias (see page 69)

Calcinosis

Calcinosis is the formation of tiny deposits of calcium underneath the skin. These deposits of calcium salts settle into the tissues of the body and become inflamed and are a source of discomfort. The deposits may come through the skin, opening a source for frequent infections. Calcium deposits, observed on x-ray in areas of the body other than the hands, may not be used to credit this symptom unless a physician has made a direct link between Scleroderma and the deposits.

Raynaud's Phenomenon

Raynaud's Phenomenon (RP) is a condition resulting in a particular series of discolorations of the fingers and/or toes after exposure to changes in temperature (cold or hot). Initially, the digit(s) involved turn white because of the diminished blood supply. The digit(s) then turn blue because of prolonged lack of oxygen. Finally, the blood vessels reopen causing a local "flushing" phenomenon which turns the digit(s) red. This three-phase color sequence (white to blue to red), most often upon exposure to cold temperatures, is characteristic of RP

This symptom may be credited if a physician has documented the presence of Raynaud's phenomenon or made the diagnosis. You do not need confirming evidence of color changes in order to credit this symptom.

Esophageal Dysmotility

Esophageal dysmotility is impaired function of the lower esophageal sphincter

Symptoms may include: intermittent heartburn, dysphagia and pain with swallowing solid food, frequent complaints of a “sticking” sensation in the throat, gastric reflux causing pooling of acid in the esophageal tract. Aspiration is often undetected but should be suspected with presentations of productive cough or pulmonary infiltrates.

Diagnostic tests may include Manometric, Cine esophagraphy, and esophagoscopy.

Sclerodactyly

Sclerodactyly is localized thickening and tightness of the skin of the fingers or toes). Clinically, sclerodactyl changes refer to the tapered fingers over which the skin atrophies. The skin becomes tight, stretched, smooth and hard over the digits [sclerosis of the skin]. Flexion contractures resulting in deformity may be present in fingers forming the classical “claw deformity” which is the defining manifestation of the term. This symptom represents progression into the atrophic disease phase. Sclerodactyly may be credited when the QMD or medical records fully describe the appearance of the fingers or if the QMD states the Claimant has sclerodactyly.

Telangiectasis

Telangiectasis are dilated capillaries that form tiny red areas, frequently on the face, hands and in the mouth behind the lips. A group or network of small vessels that become dilated, forming small focal red vascular lesions in mucous membranes and skin. Telangiectasia occurs commonly on the nail folds. Telangiectatic maculas, which are square, may involve the face, lip, tongue and hands.

Disease Option 1 Scleroderma

Severity Level C

Another way to qualify for Disease Option 1 Scleroderma, Severity Level C is if you have Limited or Intermediate Scleroderma:

Limited or Intermediate Scleroderma - Skin changes must be more than localized scleroderma and must be noted in more than one localized area, **not including the trunk**, for this severity level to be assigned. The affected areas must be noted above the digits. For example, changes may be noted on the hands, wrists, arms, shoulders, face and neck, and may also include the legs and feet.

Disease Option 1 Scleroderma Severity Level D

Level D is the “default level.” A Claimant will be approved at this level if her medical records do not support any of the other levels of compensation

or

The medical records support Localized Scleroderma, which is linear scleroderma or morphea or sclerodactyly without any CREST symptoms.

What is the difference between Disease Option 1 and 2 claims for SS?

Listed below are some of the differences:

DISEASE OPTION 2	DISEASE OPTION 1
You must be examined by a Board Certified Rheumatologist (BCR).	You can rely on the evaluation of a “Qualified Medical Doctor” or a review of your medical records by the SFDCT.
You must have a diagnosis of SS by the BCR.	You can qualify if you do not have a diagnosis of SS if the symptoms support the claim; atypical presentations and SS-Like descriptions are sufficient.
The BCR must make an affirmative statement that you do not have “Localized Scleroderma”	Statement excluding Localized Scleroderma is not required in Option 1, SS.
You must submit the physician’s office notes <u>and</u> the objective test that support your symptoms.	You must submit the medical records or a QMD evaluation that support your symptoms. You are not required to submit the objective test, if these symptoms are documented in the QMD letter or medical records.
Your symptoms must have occurred within a single 24 month period within 5 years of submitting your claim	There is no 24 month/5 year time frame requirement in Option 1.
Pre-existing SS symptoms will not be credited as eligible symptoms. You must submit a letter or statement from your BCR stating that none of your qualifying symptoms existed before you received your first breast implant.	Pre-existing SS 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.