SF-DCT INFORMATION FOR ATYPICAL CONNECTIVE TISSUE DISEASE (ACTD) CLAIMS

OPTION I

(ACTD claims are not eligible for Disease Option 2)

Atypical Connective Tissue Disease (ACTD)

- Atypical Connective Tissue Disease (ACTD) is a covered condition in Disease Payment Option 1 of the Dow Corning bankruptcy. It was also a covered condition in the original global settlement in 1994 and included in the Revised Settlement Program (RSP) in MDL-926. It is also called Atypical Rheumatic Syndrome (ARS) or Non-Specific Autoimmune Condition (NAC).
- To qualify, a claimant must meet any one of the five combinations of eligible findings or symptoms from the list of over 30 eligible ACTD symptoms.
- To submit a claim for ACTD, you do <u>not</u> need a diagnosis of ACTD. Your doctor does <u>not</u> need to state that your eligible findings and symptoms were caused by breast implants.
- •You <u>can</u> be compensated for ACTD if you have been diagnosed with "Undifferentiated Connective Tissue Disease" (UCTD), Fibromyalgia (FM) or Chronic Fatigue Syndrome (CFS).

ACTD - General

The vast majority of women who have been approved for a disease payment in the Dow Corning Settlement Facility are approved for ACTD. Claimants with approved ACTD claims can be compensated only in Disease Option 1; ACTD is not an eligible condition in Disease Option 2.

To qualify for ACTD, you must submit the following documents:

There are two (2) ways that you can qualify for ACTD:

 □ 1. A written evaluation by a "Qualified Medical Doctor" (QMD) that documents your symptoms (see pages 5-7);

AND/OR

□ 2. Written medical records from your "Treating Physician" that document your symptoms and disability, along with medical records from any other doctor you have seen that documents your symptoms (see pages 9-11).

Section 1. Qualifying for ACTD by relying on a Qualified Medical Doctor (QMD) Statement or Diagnosis

One way to qualify for ACTD is to submit a "QMD statement" or a statement such as a letter or report written by a Qualified Medical Doctor.

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. Neurology; or
- 5. Neurosurgery; or
- 6. Doctor of Osteopath with similar specialty certifications; or
- 7. 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.

Section 1. What qualifies as a statement or diagnosis by a QMD?

- A "<u>statement</u>" is a letter or report written by the QMD about your overall physical condition. It should provide details about your eligible signs and symptoms that were documented in a medical records from either the QMD's evaluation of you or your office visits to your physician(s). If you are relying solely on the QMD statement and are not submitting any medical records to the SF-DCT, then the QMD statement must contain enough information about your qualifying signs and symptoms to approve the ACTD claim and assign a disability level.
 - The report should contain more than a report of a complaint or problem.
 - A diagnosis of ACTD by the QMD is <u>not</u> required.
 - You do not have to be evaluated by the QMD; the QMD can rely on medical records from other physicians that you supplied to him/her.
- A "<u>diagnosis</u>" is a finding by the QMD regarding a sign or symptom and/or your medical condition, i.e., claimant Smith has arthralgia. A diagnosis can be found in a medical record or in a letter from the QMD or from a physician that the QMD relies upon.

Section 1. What happens if you have more than one QMD letter or statement in your file?

If your file has more than one QMD letter or statement, the Settlement Facility will credit all of the qualifying signs or symptoms listed in any of the letters or statements, if the letters or statements do not contain conflicting information.

Section 1. Acceptable signatures on the QMD letter or statement

You do not have to submit the original version of the QMD letter or statement. You can submit a copy.

The QMD <u>must</u> personally sign the QMD letter or statement. The following types of signatures are accepted in the place of the physician's personal signature:

- An electronic signature; or
- A stamped signature; or
- A notation that the letter was "Dictated but not read."

The following types of signatures are <u>NOT</u> acceptable:

- Signatures signed in the place of the physician, i.e., Dr. Steven Jones, by M. Wilson, R.N., or "signed in the absence of Dr. Jones"
- No signature or signature line left blank (unless the QMD is also your Treating Physician).

Section 2. Qualifying for ACTD by relying on medical records from your "Treating Physician"

Another way to qualify for ACTD is to rely on the medical records from a "Treating Physician." A Treating Physician is a doctor who has seen you on at least two separate occasions before writing the Settlement letter. This can be established by:

- Medical records from the same doctor that show you were seen on at least two or more occasions; or
- Statements in medical records or letters about the doctor's history of treating you. For example, Dr. Jones writes that, "I have treated Mrs. Smith for back pain for over 20 years" or "I have been Ms. Jones' primary care physician for 2 years."
- Laboratory reports that reflect that the same doctor ordered lab work for you on more than one occasion or over a period of time; or
- Letters that are addressed to your physician from other physicians regarding your condition over a period of time. For example, "Dear Dr. Jones, Thank you for referring Mrs. Jones for consultation regarding her diabetes. I am aware of your efforts to get her condition under control over the past months.")

Note: Medical records reflecting only <u>one</u> office visit from different physicians in a physician's practice group, does not establish a specific doctor as your treating physician. If you are being treated in a practice group, a physician in that practice must provide medical treatment on at least <u>two</u> occasions to be considered as your treating physician.

Section 2. Your Treating Physician must document your qualifying signs and symptoms in your medical records

- To qualify for ACTD by relying on a Treating Physician, you must submit the medical records from the Treating Physician that support your qualifying signs and symptoms. The Settlement Facility cannot credit the signs and symptoms based solely on a letter from a Treating Physician.
- The Settlement Facility <u>can</u> credit your disability level based solely on a letter from your Treating Physician.

Section 2. Your "Treating Physician" can also be a QMD

A QMD (as defined on p. 5) can also be a Treating Physician if your file reflects the following:

- The QMD who has written the statement or diagnosis for the settlement and has also seen you on at least two prior occasions before (s)he wrote the settlement letter.
- If the QMD is also the Treating Physician, the QMD's letter is <u>not</u> required to have a signature. If the QMD is not the Treating Physician, then it <u>must</u> have an acceptable signature before a disease or any level of compensation can be approved.
- A claim for ACTD cannot be approved based solely on a letter from your Treating Physician. You must also submit the medical records that document your signs and symptoms.

ACTD, Disease Option 1

Signs and Symptoms

ACTD and Rheumatoid Arthritis

If you have been diagnosed with classical Rheumatoid Arthritis (CRA), the Settlement Facility cannot credit any of the signs and symptoms of ACTD listed below:

- Polyarthritis (as defined in Group 1)
- Positive Rheumatoid Factor (Group 2)
- Documented Arthralgias (Group 3).

ACTD Signs and Symptoms are divided into 3 Groups

To qualify for ACTD, you must have a certain number of non-duplicative signs and symptoms. The signs and symptoms are divided into three groups:

Group 1 – this includes 3 signs and symptoms that are objectively documented on exam by a doctor or a diagnostic test and are considered more significant medically than signs and symptoms in Groups 2 and 3

<u>Group 2</u> – this includes 10 signs and symptoms that are also objectively documented on exam by a doctor or an abnormal test and are considered more significant medically than signs and symptoms in Group 3

<u>Group 3</u> – this includes 18 signs and symptoms that are mostly subjective (self-reported complaints of muscle pain, joint aches, etc.) but also includes some objective findings.

How to qualify for ACTD

To qualify for ACTD, you must meet any **ONE** of the following:

- 1. Any two (2) symptoms from Group 1; or
- 2. One (1) symptom from Group 1 **AND** one (1) symptom from Group 2; **or**
- 3. Three (3) symptoms from Group 2; or
- 4. Two (2) symptoms from Group 2 **AND** one (1) additional <u>non-duplicative</u> symptom from Group 3; <u>or</u>
- 5. Five (5) <u>non-duplicative</u> signs/symptoms from Group 1, Group 2 **OR** Group 3.

Non-duplicative symptoms

Certain signs and symptoms are included in more than one group, but require different levels of proof. For example, Keratoconjuctivitis Sicca (dry eyes, dry mouth) is listed as a Group 1 symptom if it is documented objectively by one of the eight listed tests <u>and</u> there is a complaint of either dry eyes or dry mouth.

If your file does not reflect a complaint of dry eyes or dry mouth, but the records reflect one of the eight listed test on page (26), the symptom will be approved in Group 3, Sicca.

Non-duplicative Symptom: If you are approved for Group I Keratoconjunctivitis Sicca, you cannot rely on the Group 3 symptom of Sicca.

Note: If the file does not contain a complaint of dry eyes or dry mouth, but the medical records reflect one of the abnormal tests on page (26), the file will be reviewed by the Claims Administrator for possible approval in Group I.

Pre-Existing Symptoms

If you have a symptom or condition that existed prior to the date of your first breast implant, the SF-DCT cannot credit or use that symptom or condition to approve any level of disability.

If a QMD determines that a symptom is clearly and specifically caused by a source other than your breast implants (i.e., the QMD states that the joint pain in your left elbow was caused by a car accident you were in), then that symptom cannot be used in the diagnosis of ACTD.

ACTD Group 1 Symptoms

There are three (3) signs and symptoms in Group 1:

- Raynaud's phenomenon (pages 20 & 21)
- Polyarthritis (pages 22-25)
- Keratoconjunctivitis Sicca (26-39)

Group 1 - Raynaud's Phenomenon (RP) and how it is credited

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.

Raynaud's Phenomenon (RP) can be credited if you have a diagnosis of RP and any **ONE** of the following:

- A diagnosis of RP and evidence by the patient giving a history of two (2) color changes. The specific colors do not have to be described in the medical records. This can be described in the medical records as "color changes", "fingers turn red to blue", "biphasic color changes" or "triphasic color changes"; or changes or "triphasic color changes"; or changes or "triphasic color changes"; or changes or
- A diagnosis of RP and evidence of vasospasms on physical exam. Vasospasm is the sudden, brief tightening or contraction of a blood vessel that limits blood flow to the tissue supplied by that vessel. The most common symptom is pain, pallor and/or a sensation of cold in the affected limb; or
- A diagnosis of RP and evidence of digital ulceration (sores) or necrosis of one or more fingertips on physical exam; **or**
- A diagnosis of RP and evidence of blueness, pallor or cyanosis of the finger tips on physical exam.

Group 1 Raynaud's Phenomenon: Unacceptable Proof

Common reasons why claimants receive a deficiency notice about the symptom of Raynaud's Phenomenon (RP):

- The medical records reflect a history of color changes but there isn't a diagnosis of RP.
- The medical records reflect a diagnosis of RP with a history of only one color change.
- The medical records reflect a diagnosis of RP without a history of any color changes.
- The medical records reflect that you were diagnosed with RP before your first breast implantation.
- The medical records reflect vasospasms, cyanosis, blueness, pallor or necrosis found on physical exam but the file does not reflect a diagnosis of RP.

Group 1 – Polyarthritis and how it is credited

Polyarthritis as defined in the Plan is inflammation (synovial swelling and tenderness) in three (3) or more joints at the same time lasting greater than six (6) weeks and observed by a physician. To receive credit for Polyarthritis in Group 1, you must submit the following:

- 1. Medical records showing that you were examined by a physician on two (2) occasions at least six (6) weeks apart; **AND**
- 2. The physician must have observed swelling <u>AND</u> pain or tenderness in three (3) or more joints at the same time; <u>AND</u>
- 3. The swelling and pain or tenderness must have lasted for at least six (6) weeks or longer; **OR**
- 4. The physician observes swelling <u>AND</u> pain or tenderness in three joints at same time on at least one physical exam, and states that the condition has lasted for at least six (6) weeks.

Group 1 Polyarthritis: Unacceptable Proof

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

- The medical records reflect only swelling or only tenderness or pain in three joints at the same time. There must be swelling <u>and</u> tenderness in three joint at the same time.
- The medical records have a diagnosis of classical Rheumatoid Arthritis (CRA) so you cannot rely on the symptom of Polyarthritis as part of your ACTD claim.
- The medical records have a diagnosis of arthritis, but do not reflect the presence of swelling and tenderness or pain on physical examination by a physician.
- The medical records reflect a diagnosis of any type of arthritis prior to the date of your first breast implantation.
- The exam found swelling and tenderness or pain on exam in fewer than three (3) joints.
- The medical records reflect only <u>complaints</u> of swelling and/or tenderness in the joints. The swelling and pain or tenderness must be observed on physical examination by a physician.

Group 1 Polyarthritis vs. Group 3 Documented Arthralgia

If a doctor notes swelling and tenderness found on exam in <u>less</u> than three joints or a <u>complaint</u> of swelling and tenderness in a specific joint (s), the Settlement Facility will credit this as a Group 3 symptom - Documented Arthralgias.

Group 1, Definition of Joint Groups for Polyarthritis

The following is a list of the joints and joint groups for Polyarthritis.

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

continued on next page

Group 1, Definition of Joint Groups for Polyarthritis

continued from prior page:

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

Group 1 – Keratoconjunctivitis Sicca (K-Sicca) and how it is credited

Keratoconjunctivitis Sicca (K-Sicca) as defined in the Plan is the subjective complaint of <u>either</u> dry eyes and/or dry mouth <u>AND</u> medical records reflecting the results of any one (1) of the following test within the same time period as the complaint of dry eyes or dry mouth:

DRY EYES:

- Lacrimal gland enlargement; or
- Abnormal Schirmer's test; or
- Abnormal Rose Bengal staining; or
- Filamentous Keratitis; or
- Dry eyes documented by Fluorescein Staining; or

DRY MOUTH:

- Salivary gland enlargement; or
- Parotid gland enlargement; <u>or</u>
- Abnormal parotid gland scan or ultrasound <u>or</u>
- Abnormal CT or MRI of the parotid <u>or</u>
- Abnormal labial salivary biopsy.

Note: If the file does not contain a complaint of dry mouth or dry eyes, but the medical records reflect one of the abnormal tests on page (26), the file will be reviewed by the Claims Administrator for possible approval in Group I.

Group 1 K-Sicca

You do not need to submit the actual lab reports if your medical records reflect the results of the test, and the results meet the Plan's requirements. However, you may want to submit a copy of the lab reports to the SF-DCT in case it contains information needed to credit the symptom.

Group 1 K-Sicca: Lacrimal Gland Enlargement for Dry Eyes

The <u>lacrimal gland</u> is located just above the outer corner of the eye and is part of the system that forms tears. To credit this symptom, the glands must be documented as enlarged.

Group 1 K-Sicca: Schirmer's Test for Dry Eyes

Schirmer's Test — This test involves placing a thin tear strip (paper) inside the lower eyelid for 5 minutes. The tear strip is then removed and the length of the strip that is wet from tears is measured and compared to a standard. Individuals with dry eyes will have less wetting of the tear strip than normal. For this symptom to be credited by the SF-DCT, the Schirmer's Test must show a result of less than 9 millimeters of wetting in 5 minutes or 10 millimeters within five minutes, if the physician notes the results as abnormal.

 The test can be performed by any medical doctor but is generally performed by an ophthalmologist. The test results must include the millimeters of wetting and the time frame in minutes.

Group 1 K-Sicca: Rose Bengal Staining for Dry Eyes

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

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

Group 1 K-Sicca: Filamentous Keratitis for Dry Eyes

Filamentous Keratitis is an inflammation of the cornea accompanied by buildup of fine filaments of mucous which binds the eye and causes severe foreign body sensation.

The symptoms include very dry eyes, thick mucous, eye pain, decreased vision and/or a thread-like appearance on the cornea.

The SF-DCT will credit the symptom if the condition is noted in the medical records.

Group 1 K-Sicca: Fluorescein Staining Test for Dry Eyes

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

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

Group 1 K-Sicca: Salivary Enlargement for Dry Mouth

There are three major <u>salivary glands</u> in the mouth that produce saliva: parotid glands, submandibular glands and the sublingual glands.

To credit this symptom, your medical records must reflect that your physician palpated the glands and documented that they were enlarged.

Group 1 K-Sicca: Parotid Enlargement for Dry Mouth

The <u>parotid gland</u> is the largest of the three major salivary glands. It is located in front and below the ear and behind the jaw bone.

To credit this symptom, your medical records must reflect that your physician palpated the glands and documented that they were enlarged.

Group 1 K-Sicca: Abnormal Parotid Scan or Ultrasound for Dry Mouth

Parotid Scan – A radioactive tracer is injected into a vein in the arm and followed by images taken by a special camera. The camera documents how much tracer stays in the parotid gland.

<u>Ultrasound</u> – This is a medical imaging technique used to see muscles, tendons and organs.

An abnormal parotid scan or ultrasound of the parotid gland will show obstruction or lack of salivary flow.

Group 1 K-Sicca: Abnormal CT or MRI for Dry Mouth

"CT" stands for "Computed Tomography" and is a medical imaging device that allows physicians to see a 3-dimensional view of your organs.

"MRI" stands for "Magnetic Resonance Imaging" and is also a medical imaging device that allows physicians to see greater soft tissue contrasts than with a CT.

An abnormal CT or MRI of the parotid gland will show swelling or an obstruction.

Group 1 K-Sicca: Abnormal Labial Salivary Biopsy for Dry Mouth

A <u>labial salivary gland biopsy</u> is the removal of one of the small glands lying beneath the mucous membrane of the lips. This is a minor, outpatient procedure using local anesthesia of the lip.

An abnormal labial salivary biopsy will show grape like clusters on the inner surface of the lips.

Group 1 K-Sicca: Unacceptable Proof

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

- Your parotid, lacrimal or salivary glands were not documented as enlarged.
- Your medical records do not reflect that you had one of the abnormal tests listed on (page 26). If your medical records reflect a complaint of dry eyes and/or dry mouth, this is sufficient to credit it as a Group 3 Sicca Symptom.
- Your medical records reflect a Schirmer's test with results of greater than 10 millimeters of wetting.
- Your medical records reflect a Schirmer's test without listing the millimeters of wetting and the time frame for the test (minutes).
- Your medical records reflect that you were diagnosed with K-Sicca before you received your first breast implant.
- Your complaint of dry eyes and/or dry mouth is dated more than one (1) year from the date of the abnormal test.
- The medical records do not reflect a complaint of dry eyes or dry mouth.
- •Your MRI, CT Scan or Ultrasound of the parotid gland do not reflect inflammation or an obstruction.

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

If you are credited with the Group 1 symptom of K-Sicca, then you cannot use the Group 3 symptom of Sicca Symptoms to qualify for ACTD.

ACTD Group 2 Symptoms

There are ten (10) signs and symptoms in Group 2:

- Myalgias (pages 41-43)
- Immune mediated skin changes or rashes (pages 44-52)
- Pulmonary symptoms or abnormalities (pages 53-59)
- Pericarditis (pages 60-62)
- Neuropsychiatric symptoms (pages 63-68)
- Peripheral neuropathy (pages 69-71)
- Myositis or Myopathy (pages 72-76)
- Serologic abnormalities (pages 77-86)
- Lymphadenopathy (page 87&88)
- Dysphagia (pages 89-94)

Group 2 – Myalgias and how they are credited

To credit this symptom, myalgias must be documented by tenderness on examination. Myalgias are muscle pain and/or tenderness in a muscle.

To receive credit for myalgias, your medical records must document **ONE** (1) of the following:

- •tenderness, tendonitis or tenosynovitis found on physical exam in a <u>specific</u> muscle, muscle group or muscle area. Tenosynovitis is when a tendon and its surrounding soft tissue become inflamed, swollen, and painful. (A less accurate and rarely used term to describe this condition is tendonitis.); <u>or</u>
- "trigger points" or "tender points" found on physical exam (no specific location needed). These are localized tender areas of the body that can bring on widespread pain and muscle spasm when touched. Tender points are commonly found around the elbows, shoulders, knees, hips, back of the head, and the sides of the breast bone.

Group 2 Myalgias: Unacceptable Proof

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

- Muscle tenderness was not found on physical exam, i.e., it was reported by you to the doctor. If you are
 not able to document muscle tenderness on physical examination, then the SF-DCT will credit your
 complaints of myalgias in a specific muscle area, a history of tenderness or pain in a specific muscle area,
 or trigger points or tender points as a Group 3 symptom -- Documented Myalgias.
- Your medical records note that your myalgias are directly related to another cause or medical condition.
- The muscle tenderness was found on exam but the specific muscle, muscle group or muscle area was not specified.
- A diagnosis of fibromyalgia, trigger points, tender points or tendonitis existed prior to the date of your first breast implant.
- Your medical records reflect that you were diagnosed with myalgias before you received your first breast implant.

Myalgias in Group 2 vs. Documented Myalgias in Group 3

If you are credited with the Group 2 symptom of Myalgias, then you cannot use the Group 3 symptom of Documented Myalgias to qualify for ACTD.

Group 2: Immune mediated skin changes or rash and how it is credited

Immune mediated skin changes or rash is defined in the Plan as changes in texture or rashes that may or may not be characteristic of SLE, Systemic Sclerosis (Scleroderma) or Dematomyositis, or diffuse petechiae, telangiectasias, or livedo reticularis.

To credit this symptom, your medical records must document any **ONE** of the following:

- description of a heliotrope rash (page 45); or
- description of Grotton's papules (page 46); or
- a vasculitic rash confirmed by biopsy (pages 47); or
- a well described rash (example: red, raised, itchy, scaly rash on the back); or
- repeated complaints of dermatitis that do not respond to treatment; or
- "skin tightening" not related to the breast area; or
- diffuse petechiae (page 48); or
- diffuse telangiectasis (page 49); or
- diffuse livedo reticularis (pages 50).

Group 2 Immune mediated skin change or rash: Heliotrope Rash

A <u>heliotrope rash</u> is a reddish-purple rash that covers the upper eyelids.

Group 2 Immune mediated skin change or rash: Grotton's papules

Grotton's papules are red, scaly lesions that cover certain joints like the knees and elbows.

Group 2 Immune mediated skin change or rash: vasculitic rash confirmed by biopsy

A vasculitic rash is red or purple dots on the skin caused when small vessels break and produce tiny areas of bleeding in the tissue. To credit this symptom in the Plan, a biopsy of the involved tissue must be taken and it must confirm that it is a vasculitic rash.

Group 2 Immune mediated skin change or rash: diffuse petechiae

Petechiae are small (less than 3 millimeters in diameter), flat round red spots under the skin surface caused by bleeding into the skin.

To credit the symptom, your medical records must state that the petechiae are <u>diffuse</u>, i.e., widely dispersed over an area.

Group 2 Immune mediated skin change or rash: diffuse telangiectasias

Telangiectasias are red, blue, or purple linear marks measuring less than 1–3 mm in width and several millimeters to centimeters in length. They are widely open (dilated) blood vessels in the outer layer of the skin. When seen on the legs, they are often called spider veins.

To credit the symptom, your medical records must state that the telangiectasias are <u>diffuse</u>, i.e., widely dispersed over an area.

Group 2 Immune mediated skin change or rash: diffuse livedo reticularis

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

To credit the symptom, your medical records must state that the livedo reticularis are <u>diffuse</u>, i.e., widely dispersed over an area.

Group 2 Immune mediated skin changes or rash: Unacceptable Proof

Common reasons why claimants receive a deficiency notice about the symptom of Immune mediated skin changes or rash:

- A rash is noted in the medical records but it is not described.
- A physician states that the rash is directly related to something other than breast implants.
- The rash is described as a photosensitive rash. If the rash is described as photosensitive, it will be credited as a Group 3 symptom Photosensitivity.
- The medical records describe the presence of petechiae, telangiectasias or livedo reticularis, but they do not describe the rash as diffuse. They must be diffuse.
- The medical records state that you were diagnosed with an immune mediated skin change or rash before you received your first breast implant.
- A vasculitic skin rash is described, but the file does not contain a biopsy report.
- A vasculitic skin rash is described, but the biopsy report does not confirm a vasculitic rash.

Immune mediated skin change or rash in Group 2 vs. Photosensitivity in Group 3

If you are credited with the Group 2 symptom of Immune mediated skin change or rash, then you cannot use the Group 3 symptom of Photosensitivity to qualify for ACTD.

Group 2: Pulmonary symptoms or abnormalities and how they are credited

Pulmonary symptoms or abnormalities are defined by the Plan as conditions that may or may not be characteristic of Systemic Lupus Erythematosus (SLE), Systemic Sclerosis (Scleroderma) or Sjogren's Syndrome.

To credit this symptom, your medical records must document at least **ONE** (1) of the following:

- Pleural Lung disease (page 35); or
- Interstitial Lung disease or Interstitial Fibrosis (page 56); or
- Restrictive Lung disease (page 57); or
- Obstructive Lung Disease (Emphysema, Asthma or Chronic Bronchitis) (page 58).

Group 2 Diagnostic Tests That May Be Used to Identify Pulmonary Abnormalities

Diagnostic Tests That May Be Used to Identify Pulmonary Abnormalities:

- 1. Blood Tests (Arterial Blood Gases)
- 2. Pulmonary Function Tests
- 3. Chest X-ray
- 4. CT Scan

Group 2 Pulmonary Abnormalities: Pleural Lung Disease

Pleural Lung Disease (PLD) is a type of Restrictive Lung Disease. To credit the symptom of Pleural Lung Disease, your medical records must document **ONE** of the following:

- The QMD letter or the medical records reflect a diagnosis of Pleural Lung Disease; **or**
- A chest x-ray that shows normal lungs, except for the presence of pleural fluid with an impression of Pleural lung Disease.

Group 2 Pulmonary Abnormalities: Interstitital Lung Disease or Interstitial Fibrosis

<u>Interstitial Lung Disease (ILD)</u> or <u>Interstitial Fibrosis</u> is a general term that includes a variety of chronic lung disorders. The lung tissue is damaged and the walls of the air sacs in the lung become inflamed. Scarring (or fibrosis) begins in the tissue between the air sacs, and the lung becomes stiff.

To credit the symptom of Interstitial Lung Disease, your medical records must document **ONE** the following:

- The QMD letter or the medical records must reflect a diagnosis of Interstitial Lung Disease or Interstitial Fibrosis.
- A chest X-ray which shows increased abnormal markings along with an impression of Interstitial lung disease or Interstitial Fibrosis.

Note: The SF-DCT does not credit the condition of Pulmonary Fibrosis

Group 2 Pulmonary Abnormalities: Restrictive Lung Disease

Restrictive Lung Disease (RLD) is a decrease in the total volume of air that the lungs are able to hold. RLD's cause a loss of lung tissue, decrease in the lung's ability to expand, and/or a decrease in the lung's ability to transfer oxygen or carbon dioxide with the blood.

To credit the symptom of Restrictive Lung Disease, your medical records must document the following:

A diagnosis of RLD in the QMD letter or the medical records.

Group 2 Pulmonary Abnormalities: Obstructive Lung Disease

<u>Obstructive Lung Diseases</u> (OLD's) cause a narrowing or blockage of the airways resulting in a decrease in exhaled air flow. Examples of OLD's are:

- Chronic Obstructive Pulmonary Disease (COPD)
- Emphysema
- Asthma
- Chronic Bronchitis

To credit the symptom of OLD, your medical records must document characteristic clinical findings **and ONE** of the following diagnostic test :

- Abnormal chest X-ray changes reflecting normal or hyper-inflated lungs with a flattened diaphragm and possible bullae present, in a <u>smoker</u> or a <u>non-smoker</u>.
- An abnormal pulmonary function study showing all of the following in a <u>non-smoker</u>:
 - 1. normal or low FVC (forced vital capacity); and
 - 2. low FEV1 (forced expiratory volume in 1 second) < 80% predicted; and
 - 3. TLC (total lung capacity) normal or high; and
 - 4. Decreased DLCO (diffuse level of carbon monoxide).

Group 2 Pulmonary Abnormalities: Obstructive Lung Disease (cont'd)

 Abnormal Arterial blood gases (ABG's) in a <u>smoker</u> or a <u>non-smoker</u>. In order to receive credit for this symptom, your test results must be <u>outside</u> of the normal values noted below:

Normal blood gas values are as follows:

- partial pressure of oxygen (PaO2): 75-100 mm Hg
- partial pressure of carbon dioxide (PaCO2): 35-45 mm Hg
- oxygen content (O2CT): 15-23%
- oxygen saturation (SaO2): 94-100%
- bicarbonate (HCO3): 22-26 mEq/liter
- pH: 7.35-7.45

Group 2 Pulmonary symptoms or abnormalities: Unacceptable Proof

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

- The medical records note that you have a diagnosis of COPD, but you did not submit records with the clinical findings (physical examination) or the results of one of the tests listed on pages 58 & 59.
- The medical records note that you have a diagnosis of COPD with an abnormal pulmonary function test, but you are currently a smoker. To qualify, you must be a non-smoker for at least 15 years prior to the time the test is performed.
- The medical records note that you have a diagnosis of COPD, but the chest x-ray results do not show normal or hyper-inflated lungs with a flattened diaphragm.
- The medical records note a diagnosis of COPD with an abnormal pulmonary function but the claimant has not been smoke free for at least fifteen years.
- The medical records directly relate your pulmonary abnormalities to smoking or other medical conditions or causes.
- The medical records note that you have been diagnosed with one of the pulmonary conditions before you
 received your first breast implant.
- The medical records reflect a diagnosis of COPD and clinical findings but your file reflects normal arterial blood gases.
- Your file reflects clinical findings of COPD but the file reflects a diagnosis of Pulmonary Fibrosis.

Group 2 Pericarditis and how it is credited

<u>Pericarditis</u> is an inflammation of the lining sac (pericardium) that surrounds the heart. Chest pain is the most common symptom. Other symptoms can include weakness, fever, and chills.

To receive credit for the symptom of Pericarditis, your medical records must document <u>consistent</u> clinical findings of Pericarditis **AND ONE** (1) of the following:

- Electrocardiogram (EKG) test results that document Pericarditis; or
- Echocardiogram (ECG) test results that document Pericarditis.

Group 2 Pericarditis

An <u>Electrocardiogram</u> (EKG) is a recording of the heart's electrical activity. To credit the symptom of Pericarditis in the Plan, the EKG results must confirm a diagnosis of Pericarditis.

An <u>Echocardiogram</u> (ECG) uses ultrasound waves to make images of the heart chambers and pericardial space. It can detect and measure the amount of fluid around the heart. To credit the symptom of Pericarditis in the Plan, the ECG results must confirm a diagnosis of Pericarditis.

Group 2 Pericarditis: Unacceptable Proof

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

- The file does not reflect any of the clinical findings such as chest pain, fever, precordial or friction rub heard on physical examination.
- The EKG or ECG test results do not confirm a diagnosis of Pericarditis.
- Your reflects a diagnosis of Pericarditis before you received your first breast implant.
- The medical records directly relate your Pericarditis to another cause or medical condition.

Group 2 Neuropsychiatric Symptoms and how they are credited

Neuropsychiatry is the branch of medicine that deals with mental disorders attributable to diseases of the nervous system.

To receive credit for Neuropsychiatric Symptoms, your medical records must give examples of your <u>cognitive dysfunction</u> (memory loss and/or difficulty concentrating) which may be characteristic of SLE or MCTD that is documented by <u>ONE</u> (1) of the following <u>and</u> the physician must make the connection between your memory loss and the abnormal test:

- An abnormal SPECT scan; or
- An abnormal PET scan; or
- An abnormal MRI; or
- An abnormal EEG; or
- An abnormal result from Neuropsychological Testing (a mental status exam).

Note: If you have an abnormal test but only a history of cognitive problems without specific examples of memory loss or difficulty concentrating, and the physician makes reference of the abnormal test, the file will be reviewed by the Claims Administrator for possible approval in Group 2.

Group 2 Neuropsychiatric Symptoms: SPECT and PET Scans

<u>SPECT Scan</u> – SPECT stands for <u>Single Photon Emission Computerized</u>
<u>Tomography.</u> It uses a radioactive substance and a special camera to produce three-dimensional images that show what areas of your brain are more or less active. To credit the test, the brain SPECT must show abnormal brain waves suggestive of a neuropsychiatry diagnosis; <u>or</u>

PET Scan – PET scan stands for **Positron Emission Tomography**. A small dose of radioactive tracer is injected into your arm and, as it travels through the body, images are taken that show how the organs and tissues in your body are functioning. It measures blood flow, oxygen use and glutose metabolism, and can be used to evaluate patients who have memory disorders, suspected or proven brain tumors or seizure disorders. Different colors or degrees of brightness on the images from a PET scan represent different levels of tissue and organ function. To credit Neuropsychiatric Symptoms, the brain PET must show abnormal brain waves suggestive of a neuropsychiatry diagnosis.

Group 2 Neuropsychiatric Symptoms: MRI and EEG Tests

MRI stands for Magnetic Resonance Imaging. MRI uses a powerful magnetic field, radio waves and a computer to produce detailed pictures of organs, soft tissues, bone and internal body structures. To credit the symptom of Neuropsychiatric Symptoms, the MRI results of the brain must show abnormal brain waves suggestive of a neuropsychiatry diagnosis; or

EEG stands for ElectroEncephaloGram (EEG). It is a test that measures and records the electrical activity of your brain. The computer records your brain's electrical activity as wavy lines. To credit the symptom of Neuropsychiatric Symptoms, the EEG results must be abnormal, i.e., the two sides of the brain show different patterns of electrical activity, or the EEG shows sudden bursts of electrical activity (spikes) or sudden slowing of brain waves in the brain, or the EEG records changes in the brain waves that may not be in just one area of the brain, or the EEG shows delta waves or too many theta waves in adults who are awake. To credit the symptom of Neuropsychiatric Symptoms, the EEG results of the brain must show abnormal brain waves suggestive of a neuropsychiatry diagnosis.

Group 2 Neuropsychiatric Symptoms: Neuropsychological Testing

Neuropsychological Tests are objective tests used to evaluate brain function and a patient's mental status. To credit Neuropsychiatric Symptoms, you must submit the written results of a neuropsychological test (mental status exam) that should reflect **ALL** of the following:

- General appearance, behavior, motor activity,
- Affective reactions, thought flow and content,
- Perceptions, memory, and orientation and level of consciousness,
- Specific evidence and a detailed description of memory loss or deceased concentration.

Group 2 Neuropsychiatric Symptoms: Unacceptable Proof

Common reasons why claimants receive a deficiency notice about Neuropsychiatric Symptoms:

- Your medical records state that you have experienced memory loss but you did not submit the results from one of the tests listed on pages 63-66.
- Your medical records state that you have experienced memory loss but the test results from one of the tests listed on pages 63-66 are not abnormal or do not meet the Plan's requirements.
- Your medical records state that you have experienced memory loss but the test results do not meet criteria.
- Your medical records include an abnormal test result for one of the tests listed on pages 63-66 but there is no description in the medical records that you have experienced memory loss.
- Your physician directly relates the neuropsychiatric symptoms to another cause or medical condition.
- Your medical records show that you were diagnosed with a neuropsychiatric disorder before you received your first breast implant.
- Your medical records show an abnormal mini mental status exam, counting exam or memory test but there is no statement that you experienced memory loss.
- Your medical records show examples of memory loss and an abnormal test, but the physician did not make the connection between the abnormal test and your memory loss.

Note: If you have an abnormal test and only a history of cognitive problems without specific examples of memory loss or difficulty concentrating, and the physician makes reference of the abnormal test, the file will be reviewed by the Claims Administrator for possible approval in Group 2.

Group 2 Neuropsychiatric Symptoms vs. Group 3 Documented Neurological symptoms

If you are credited with Group 2
Neuropsychiatric Symptoms, then you cannot use the Group 3 Documented Neurological symptoms (Cognitive Dysfunction) to qualify for ACTD.

Group 2 Peripheral Neuropathy and how it is credited

Peripheral neuropathy is a problem with the nerves that carry information to and from the brain and spinal cord that can cause

numbness, weakness, pricking sensations, sensitivity to touch, burning pain, loss of sensation and/ or reflexes, and muscle weakness.

To receive credit for Peripheral Neuropathy, your medical records must document <u>one</u> (1) of the following symptoms found on physical exam or by history of a complaint:

- Loss of sensation to pinprick, vibration, touch or position; or
- Tingling, paresthesia (pricking sensations), or burning pain in the extremities, <u>i.e.</u>, hands, arms, feet, legs-<u>noted by history or on exam</u> <u>or</u>
- Loss of tendon reflex, noted as absent, decreased or abnormal; or
- Proximal or distal muscle weakness below 5 (loss of muscle strength in extremities or weakness of ankles, hands or foot drop). This means a strength rating of 4 or less on a scale of 1-5; or
- Signs of dysesthesia, <u>i.e.</u>, impairment of sensitivity to touch usually described as a severe burning sensation; <u>or</u>
- Entrapment Neuropathies, <u>i.e.</u>, pain and/or loss of function of the nerves as result of chronic compression, as documented by positive tinel's or positive phalen's(gentle pressure is applied to the nerve evoking a pricking sensation (paresthesia)).

Group 2 Peripheral Neuropathy: Unacceptable Proof

Common reasons why claimants receive a deficiency for Peripheral Neuropathy:

- The symptoms were not found on exam.
- You were diagnosed with a Peripheral Neuropathy in the same nerve area before you received your first breast implant.
- Your physician states that the Peripheral Neuropathy is directly related to another medical condition or cause.

Note: If symptoms are not found on exam and are noted by history only in a <u>specific</u> area, then the SF-DCT will credit the symptom in Group 3, Documented Neurological symptoms.

Group 2 Peripheral Neuropathy vs. Group 3 Documented Neurological symptoms

If you are credited with Group 2 Peripheral Neuropathy, then you cannot use the Group 3 Documented Neurological symptoms to qualify for ACTD.

Group 2 Myositis or Myopathy and how it is credited

Myositis is a general term for inflammation of the muscles. Myopathy is a disease or condition that affects the skeletal muscles.

To receive credit for Myositis or Myopathy, your medical records must note **ONE** (1) of the following:

- Muscle weakness found on physical exam in a muscle, muscle group or muscle area. The doctor should describe the affected muscle, group or area; or
- Muscle weakness found on muscle strength testing with a grade strength of less than 5 in a muscle, muscle group or muscle area; or
- An abnormal Creatine Kinase (CPK, CP or CK) or Aldolase laboratory test; or
- An abnormal Cybex Testing; or
- An abnormal EMG; or
- An abnormal muscle biopsy reflecting fiber generation or regeneration or necrosis.

Group 2 Myositis or Myopathy: Abnormal CPK or aldolase test

Serum muscle enzymes are measured by a blood test. To credit an abnormal CPK or aldolase test, you must submit a lab report test that shows that **ONE** (1) of the following enzymes is elevated:

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

Group 2 Myositis or Myopathy: Cybex Testing and EMG

Cybex Testing is a fitness test where patients are connected to a special machine that collects information about joint movement. An abnormal test result must show a decrease in muscle strength and confirms a diagnosis of Myositis or Myopathy.

<u>EMG</u> stands for <u>ElectroMyography</u> and tests the electrical activity of muscles. An abnormal result must confirm a diagnosis of Myositis or Myopathy.

Group 2 Myositis or Myopathy: Muscle Biopsy

A <u>Muscle Biopsy</u> can be done either by a needle or through surgical removal of several samples from the muscle site. An abnormal result will be reflected in a pathology report reflecting fiber generation or regeneration or necrosis.

Group 2 Myositis or Myopathy: Unacceptable Proof

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

- Muscle weakness is noted by history but is not found on exam.
- You have a diagnosis of Myositis or Myopathy before the date of your first breast implant.
- Your medical records reflect a diagnosis of Myositis or Myopathy but the file does not contain an abnormal test, or evidence of muscle weakness found on physical examination.
- Your physician directly relates your Myositis or Myopathy to another cause or condition.
- Muscle weakness is found on exam but the doctor did not note the particular muscle, muscle group or muscle area that was affected.
- Your medical records reflect a diagnosis of Myositis or Myopathy but the file reflects a normal CPK or aldolase test, and the file does not reflect evidence of muscle weakness found on physical exam.

Group 2 Serologic Abnormalities and how they are credited

Serological Abnormalities are documented by a blood test. To receive credit for Serological Abnormalities, your medical records must document the results of ONE (1) of the following lab tests (you can submit your physician's office records that record or reference the results of the test, the actual lab test results or your QMD can reference the positive ANA result in his/her letter):

- Abnormal ANA in titer or international units (I.U.) that is greater than or equal to 1:40; or
- A positive ANA Profile of any one of the following:
 - Anti-DNA
- SSA

SSB

RNP

SM-Smith

Scl-70

- CentromereJo-1

Pm-Scl

- dsDNA
 Deoxynucleoproein
- Histone

Ma

RANA

SI

- NSpll
 nuceolar and nuclear matrix;

Group 2 Serologic Abnormalities and how they are credited

(continued from page):

- Any <u>one</u> of the other antibodies listed below with <u>abnormal</u> or <u>elevated</u> results as appropriate: (Abnormal means the result is outside of the lab's reference range for that person's age and gender).
 - Thyroid Peroxidase Antibody (TPOAb), aka thyroid antibodies, aka antimicrosomal
 - thyroid stimulating immunoglobuin (TgAB)
 - anti-cardiolipin
- anti-phospholipid
- lymphocytes
- cytomplasmic
- anti-smooth, striated and skeletal
- an elevated Rheumatoid Factor reflected in ratio or international units; or
- An <u>elevated</u> Immunoglobulin: IgG, IgA, IgM; <u>or</u>
- An <u>elevated</u> Erythrocyte or Western Sedimentation Rate (ESR); <u>or</u>
- AN <u>elevated</u> C-Reactive Protein (CRP).

Group 2 Serological Abnormalities

ANA stands for Antinuclear Antibody and it is a blood test that is used to detect autoimmune diseases. The titer level of the ANA is a measure of the amount of the antibody present. To credit a positive ANA result for ACTD, the result must be greater or equal to 1:40.

Group 2 Serological Abnormalities: ANA Profile and Autoantibodies

An ANA Profile typically tests for the presence of autoantibodies (proteins that react with our own body constituents in the blood or in cells). They mistakenly target and damage specific tissues or organs of the body. To credit the symptom of Serological Abnormalities, you must have an abnormal result to one of the following antibodies:

Antibodies that are associated with Systemic Lupus Erythematosus (SLE):

anti-DNA Anti-ds DNA

anti-SSA RF

Anti-Sm (Smith)
Histone
Anti-RNP
Cardiolipin

Antibodies that are associated with Sjogren's Syndrome:

 Anti-SSA or SSB
 Anti-RNP

 Anti-ds DNA
 Anti-Scl-70

 RF
 Anti-SM (Smith)

Antibodies that are associated with Scleroderma:

Anti-Scl-70 Anti-ds DNA

 Centromere
 RF

 Pm-Scl
 Anti-RNP

Antibodies that are associated with Polymyositis, Dermatomyositis or Myositis:

Anti-Jo-1 Anti-Scl-70

Antibodies that are associated with Mixed Connective Tissue Disease:

 Anti-RNP
 Anti-ds DNA

 RF
 Anti-Jo-1

 Anti-RNP
 Anti-Scl-70

Anti-SM (Smith)

Group 2 Serological Abnormalities: Other Antibodies

Thyroid antibodies

Thyroid stimulating hormone receptor antibody (TRAb)

Anti-microsomal (aka Thyroid Peroxidase antibody, TPOAb)

Anti-cardiolipin

RF

Phospholipid

Lymphocytes

Cytomplasmic

Anti-smooth, striated and skeletal

Group 2 Serological Abnormalities: Positive Rheumatoid Factor (RF)

Rheumatoid Factor is an immunological marker (antibody) that has it associated with rheumatic diseases when it is found in high titers.

To receive credit for a positive RF, the lab report or physician must state "**Elevated**" and not abnormal or positive.

Group 2 Serological Abnormalities: Elevated Immunoglobulins

- Immunoglobulins are a large family of proteins, also known as antibodies, that protect the body from foreign pathogens.
- Immunoglobulin A (IgA) is a type of antibody that protects against infections of the mucous membranes lining the mouth, airways, and digestive tract.
- IgD, immunoglobulin D is mainly found on the surface of B-cells and may help regulate B-cell function.
- <u>IgE, immunoglobulin E</u> IgE is frequently increased in parasitic infestations and atopic individuals.
- <u>IgG, immunoglobulin G</u> the major antibody found in the blood that can enter tissues. It coats germs, helping other cells to seek and destroy them.
- IgM, immunoglobulin M an antibody that remains in the bloodstream where it can kill bacteria that enter the blood stream.

Group 2 Serological Abnormalities: <u>elevated</u> Erythrocyte or Western Sedimentation Rate (ESR)

Erythrocyte Sedimentation Rate (ESR) (also called a sedimentation rate or sed rate) is the rate at which red blood cells separate in a period of 1 hour. It is a non-specific measure of inflammation.

Group 2 Serological Abnormalities: Elevated CRP

C-Reactive Protein or CRP is a measure of inflammation and is used to predict a person's cardiovascular risk.

The lab report or physician must state "Elevated" and not abnormal or positive.

Group 2 Serologic Abnormalities: Unacceptable Proof

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

- ANA laboratory results are less than 1:40
- Erythrocyte or Western Sedimentation Rate (ESR) are not elevated.
- Elevated Immunoglobulins related to Epstein Barr, Hepatitis, CMV and/or herpes.
- Rheumatoid Factor is within normal limits
- ANA is reported as "abnormal" without a numeric value.
- Abnormal or elevated laboratory results existed prior to the date of the first breast implantation.
- Abnormal laboratory results are directly related to another cause or medical condition.
- The file does not contain any abnormal laboratory findings.
- If you are diagnosed with classical Rheumatoid Arthritis, the SF-DCT cannot credit a Serological Abnormality based solely on a positive Rheumatoid Factor result.

Group 2 Lymphadenopathy and how it is credited

Lymphadenopathy is swollen or enlarged lymph nodes.

To receive credit for Group 2 Lymphadenopathy, your file must document **ONE** of the following:

- A history of lymph node(s) measuring one centimeter (1 cm) or greater; or
- Lymph node(s) found on physical exam measuring one centimeter or greater; or
- An imaging test (MRI, CT, chest x-ray) documenting lymph node(s) measuring one centimeter or greater.

Group 2 Lymphadenopathy: Unacceptable Proof

Common reasons why claimants receive a deficiency notice about the symptom of Group 2 Lymphadenopathy:

- The Lymph node measures less than one centimeter.
- Lymphadenopathy is directly related to other causes such as colds, infections, cancer, etc.
- Documentation that swollen lymph nodes existed prior to the date of your first breast implantation in a certain area and are in the same area post-implantation.
- A diagnosis of Lymphadenopathy existed prior to the date of the first breast implantation

Note: Pre-implant Lymphadenopathy <u>can</u> be credited post implant, if the enlarged lymph nodes are found in a different area post implantation.

Note: Lymph nodes measuring less than 1 centimeter will be credited in ACTD Group 3 Lymphadenopathy.

Group 2 Dysphagia and how it is credited

Dysphagia is difficulty swallowing.

To receive credit for Dysphagia, your file must document **ONE** of the following abnormal tests:

- 1. A positive Cine-Esophagram; or
- 2. A positive imaging test; or
- 3. Manometry test; or
- 4. Motility studies; or
- 5. Increased sphincter pressure.

Note: A complaint of difficulty swallowing without an abnormal test will be credited in Group 3 Dysphagia.

Group 2 Dysphagia – Cine- Esophagram test

Cine Esophagram – This study is a series of rapid x-rays of the upper GI (gastro intestinal) series which focuses upon the swallowing mechanism.

Group 2 Dysphagia – imaging test

Imaging Tests – An endoscope is passed into the esophagus and projects images of the inside of the pharynx and esophagus on a screen for evaluation.

Group 2 Dysphagia - Manometry

Manometry is the recording of muscle pressures within an organ. An Esophageal manometry is a test that measures the timing and strength of esophageal contractions and muscular valve relaxations.

Group 2 Dysphagia – motility studies

Motility studies evaluate the pressure of the esophagus in various stages along its length. A technician places a catheter into the nose and guides it into the stomach. Once placed, the catheter is slowly withdrawn, allowing it to detect pressure changes and to record information for later review.

Group 2 Dysphagia: Unacceptable Proof

Common reasons why claimants receive a deficiency notice about the symptom of Group 2 Dysphagia:

- The medical records reflect a complaint of dysphagia or difficulty swallowing but the file does not contain one of the acceptable tests.
- The medical records directly relate dysphagia to a hiatal hernia or reflux.
- The diagnosis of Dysphagia existed prior to the date of your first breast implantation.
- Complaints of difficulty swallowing existed prior to the date of your first breast implantation.

ACTD Group 3 Signs and Symptoms

There are **18 signs and symptoms** in ACTD Group 3:

- 1. Documented Arthralgias
- 2. Documented Myalgias
- 3. Chronic Fatigue
- 4. Lymphadenopathy
- 5. Documented Neurological symptoms including cognitive dysfunction or paresthesia
- 6. Photosensitivity
- 7. Sicca Symptoms
- 8. Dysphagia
- 9. Alopecia
- 10. Sustained balance disturbances
- 11. Documented sleep disturbances
- 12. Easy bruisability or bleeding disorder
- 13. Chronic cystitis or bladder irritability
- 14. Colitis or bowel irritability
- 15. Persistent low grade fever or night sweats
- 16. Mucosal ulcers confirmed by physician
- 17. Burning pain in the chest, breast, arms or axilla, or substantial loss of function in the breast due to disfigurement or other complications from implants or explantation
- 18. Pathological findings: granulomas or siliconomas or chronic inflammatory response, or breast infections

Group 3, Symptom 1: Documented Arthralgias

<u>Arthralgia</u> is a complaint of joint pain. To receive credit for the symptom of <u>Arthralgia</u>, your file must document <u>ONE</u> of the following:

- The medical records reflect multiple notations of "arthralgias"; or
- The medical records reflect at least 2 complaints of joint pain; or
- Pain or tenderness found in a specific joint on physical exam; or
- Multiple medical records or a single record reflect complaints of joint pain over a period of time.
- Medical records reflect a notation of "generalized arthralgias or joint pain"; or
- Medical records reflect a notation of "arthralgias all over"; or
- Medical records reflect a notation of "diffuse arthralgias"; or
- Medical records reflect complaints of bursitis in a specific joint; or
- Medical records reflect Degenerative Joint Disease in a specific joint; or
- Medical records reflect Costochondritis in a specific joint; or
- Medical records reflect a history or a complaint of Temporal Mandibular Joint pain (TMJ).

Group 3, Symptom 1: Unacceptable Proof for Documented Arthralgias

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

- Medical records do not reflect at least two complaints of joint pain.
- Medical records reflect a diagnosis of Arthritis prior to the date of your first breast implantation.
- Medical records reflect a diagnosis of Classical Rheumatoid Arthritis.
- Medical records reflect complaints of stiffness only but no pain.
- Medical records reflect a notation of joint pain or arthralgias without documenting the specific joint.
- Medical records directly relate joint pain to another cause or medical condition.
- Medical records reflect a complaint of arthralgias or joint pain prior to the date of your first breast implantation without identifying a specific location.
- Medical records reflect a diagnosis of Degenerative Disc Disease and not Degenerative Joint Disease.
- Medical records reflect a diagnosis of Degenerative Joint Disease and/or bursitis without documenting the specific joint prior to the date of the first breast implantation.
- Medical records document swelling and stiffness only in a specific joint but no pain.
- Medical records reflect a notation of either "generalized, diffuse or all over" joint pain prior to the date of the first breast implantation.

Group 3, Symptom 2: Documented Myalgias

Myalgias is a complaint of muscle pain. To receive credit for the symptom of Myalgias, your file must document **ONE** of the following:

- The medical records reflect multiple notations of "myalgias"; or
- The medical records reflect multiple (2) complaints of muscle pain; or
- Multiple medical records or a single record reflect complaints of muscle pain over a period of time.
- Medical records reflect a notation of "generalized myalgias or muscle pain"; or
- Medical records reflect a notation of "myalgias all over"; or
- Medical records reflect a notation of "diffuse myalgias"; or
- Medical records reflect a history or complaints of either trigger points or tender points.
- Medical records reflect a history or a complaint of tendonitis in a <u>specific</u> muscle; <u>or</u>
- Medical records reflect a history or a complaint of muscle spasms in a <u>specific</u> muscle; <u>or</u>
- Medical records reflect a history or a complaint of muscle tightness in a specific muscle area; or
- Medical records reflect a history or a complaint of tendonitis in a specific muscle.

Group 3, Symptom 2: Unacceptable Proof for recognized Myalgias

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

- Medical records do not reflect at least two complaints of muscle pain.
- Medical records reflect a diagnosis of myalgias prior to the date of the first breast implantation.
- Medical records reflect a notation of muscle pain or myalgias without documenting the specific muscle.
- Medical records directly relate muscle pain to another cause or condition.
- Medical records reflect a diagnosis of trigger points or tender points prior to the date of the first breast implantation.
- Medical records reflect a diagnosis of Fibromyalgia prior to the date of the first breast implantation.
- Medical records reflect a diagnosis of tendonitis prior to the date of the first breast implantation.
- Medical records reflect a diagnosis of Degenerative Disc Disease in a specific muscle area.
- Medical records reflect a notation of either "generalized, diffuse or all over" muscle pain prior to the date of the first breast implantation.

Group 3, Symptom 3: Chronic Fatigue

To receive credit for Chronic Fatigue, your file must document **ONE** of the following:

- The medical records reflect a diagnosis of chronic, sustained, or persistent fatigue; or
- The medical records reflect multiple complaints or a history of being tired, fatigued or lethargic for 60 days or more.

Group 3, Symptom 3: Unacceptable Proof for Chronic Fatigue

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

- Fatigue cannot be established as chronic.
- Medical records reflect only <u>one</u> notation of fatigue.
- Medical records reflect a level of activity that contradicts the diagnosis of chronic fatigue around the same time as the diagnosis of chronic fatigue.
- Chronic fatigue is directly related to another cause or medical condition.
- Fatigue is not <u>described</u> as chronic.
- A diagnosis of Chronic Fatigue existed prior to the date of your first breast implantation.

Group 3, Symptom 4: Lymphadenopathy

The symptom of Lymphadenopathy can be credited if the file documents any **ONE** of the following:

- The medical records reflect a diagnosis of "Lymphadenopathy"; or
- The medical records document "enlarged lymph nodes": or
- Shoddy or Shotty nodes found on MRI, CT scan, X-ray, mammogram, or any other diagnostic test.

Group 3, Symptom 4: Unacceptable Proof for Lymphadenopathy

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

- The medical records reflects a history of lymph nodes without a indication of the nodes being enlarged.
- The medical records directly related enlarged lymph nodes to another cause or medical condition.
- Enlarged lymph nodes existed in the same area pre-implant and post implantation.
- The medical records describe the size of lymph node(s) as small or tiny.
- A diagnosis of Lymphadenopathy existed prior to the date of the first breast implantation.

Group 3, Symptom 5: Documented Neurological Symptoms

To receive credit for Documented Neurological Symptoms, you must document **ONE** of the following symptoms:

- 1. Cognitive Dysfunction; or
- 2. Paresthesia; or
- 3. "Other Symptoms" any other neurological symptoms of ANDS, GCTS or SLE.

Note: If one of the above three symptoms existed prior to the date of your first breast implantation, you may still receive credit for one of the other symptoms if your file meets criteria for that symptom.

Group 3, Symptom 5: Documented Neurological Symptoms – "Cognitive Dysfunction"

Cognitive Dysfunction can be credited if the file document any **ONE** of the following:

- A detailed description of memory loss or loss of concentration; or
- An abnormal mini-mental exam; or
- An Abnormal memory test; or
- Abnormal results from a counting exercise on physical examination; or
- An abnormal neuro-psychological test only.

Note: Although Cognitive Dysfunction is a documented symptom there must be a description of memory loss or loss of concentration or abnormal test to receive credit. Complaints of memory loss <u>alone</u> is not sufficient to credit the symptom.

Group 3, Symptom 5: Unacceptable Proof for Cognitive Dysfunction

Common reasons why claimants receive a deficiency notice about the symptom of Cognitive Dysfunction for Neurological Symptoms:

- The Medical records do not provide sufficient examples of memory loss or loss of concentration.
- The medical records reflect complaints of memory loss or loss of concentration only but no examples.
- The medical records directly relate cognitive dysfunction to another cause or medical condition.
- Memory loss or loss of concentration existed prior to the date of your first breast implantation.

Group 3, Symptom 5: Documented Neurological Symptoms – "Paresthesia"

The symptom of Paresthesia can be credited if the file document any **ONE** of the following:

- At least two complaints of paresthesias in a specific extremity; or
- A history of numbness, tingling, and/or prickling in a specific extremity diagnosed as "paresthesia".
- A history of numbness and tingling in specific extremity diagnosed as "Radiculopathy".

Group 3, Symptom 5: Unacceptable Proof for Paresthesia

Common reasons why claimants receive a deficiency notice about the symptom of Documented Neuro-Paresthesia:

- The medical records reflect a diagnosis of Paresthesia without documenting the specific area.
- The medical records reflect a complaint of tingling, numbness and/or prickling sensation but there is no diagnosis of paresthesia or radiculopathy.
- The medical records directly relate the diagnosis of paresthesia or radiculopathy to another cause or medical condition.
- A diagnosis of paresthesia or radiculopathy existed prior to the date of the first breast implantation.
- The medical records reflect only <u>one</u> complaint of paresthesias.

Group 3, Symptom 5: Documented Neurological Symptoms – "Other"

"Other" Documented Neurological Symptoms can be credited if the file documents any **ONE** of the following:

- A history of or a complaint of tingling, numbness or prickling in a specific extremity; or
- A history of or at least two complaints of tingling, numbness and/or prickling; or
- A history of or a complaint of seizures <u>unrelated</u> to another cause or medical condition; <u>or</u>
- A history of or a complaint of tremors, twitches, dysesthesias and/or weakness in a specific extremity; or
- Any other neurological symptoms found in the following settlement diseases/ conditions: ANDS, GCTS or SLE.

Group 3, Symptom 5: Unacceptable Proof for "Other" Neurological Symptoms

Common reasons why claimants receive a deficiency notice about the symptom of "Other" Neurological Symptoms:

- The medical records directly relate seizures, tremors or other neurological conditions to another cause or medical condition.
- The medical records reflect a complaint of numbness, tingling, weakness and/ or prickling sensation, but the records do not identify the specific extremity.
- The medical records reflect only one complaint of numbness, tingling, weakness and/or prickling sensation.
- The medical records directly relate neurological symptoms to another cause or medical condition.
- Neurological symptoms existed prior to the date of your first breast implantation.

Group 3, Symptom 6: Photosensitivity

The symptom of Photosensitivity can be credited if the file documents any <u>ONE</u> of the following:

- The QMD or medical records reflect a diagnosis of "Photosensitivity";
 or
- The QMD or medical records reflect a diagnosis of "sun sensitivity", or "photo-dermatitis"; or
- The QMD or medical records documents that the claimant's immune mediated skin rash reacts to sunlight; <u>or</u>
- The medical records directly relates a skin reaction or skin rash to sun exposure.

Group 3, Symptom 6: Unacceptable Proof for Photosensitivity

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

- Medical records reflect a diagnosis of photophobia.
- The medical records relate sun sensitivity to the eyes.
- The medical records relate diagnosis of photosensitivity to sunburn.
- The medical records relate diagnosis of photosensitivity to the eyes.
- The medical records do not describe the sun reaction as a rash, but as nausea, vomiting, headache, weakness etc.

Group 3, Symptom 7: Sicca Symptoms

The symptom of Sicca can be credited if it the file documents any **ONE** of the following:

- The medical records document history of dry eyes and/or dry mouth;
 or
- The medical records document a diagnosis of "Sicca"; or
- The medical records document a notation that claimant puts drops in her eyes and/or keeps a glass of water at the bedside; or
- The medical records document a history of "mouth feels like cotton";
 or
- The medical records reflect a diagnosis of xerostomia or xeropthalmia.

Group 3, Symptom 7: Unacceptable Proof for Sicca Symptoms

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

- The medical records reflect a history or complaints of eye irritation only.
- The medical records reflect complaints of food getting stuck in the mouth only.
- The medical records directly relate sicca to another cause or medical condition.
- A diagnosis of Keratoconjunctivitis Sicca existed prior to the date of your first breast implantation.

Group 3, Symptom 8: Dysphagia

The symptom of Dysphagia can be credited if the file documents any **ONE** of the following:

- Complaints of difficulty swallowing; or
- A diagnosis of Dysphagia; or
- Medical records reflect complaints of difficulties that interfere with swallowing such as "feelings of swelling in the throat".

Grup 3, Symptom 8: Unacceptable Proof for Dysphagia

Common reasons why claimants receive a deficiency notice for the symptom of Group 3 Dysphagia:

- The medical records reflect a complaint or diagnosis of <u>dysphasia</u> (difficulty speaking) and not <u>dysphagia</u>.
- The medical records directly relate dysphagia to another cause or medical condition.
- A diagnosis of dysphagia existed prior to the date of your first breast implantation.
- The medical records document complaints of difficulty swallowing prior to the date of your first breast implantation.

Group 3, Symptom 9: Alopecia

Alopecia is the lack of hair or the loss of hair from areas of the body where hair is usually found.

To receive credit for Alopecia, your file must document **ONE** of the following:

- The medical records document a diagnosis of Alopecia; or
- The medical records document "hair loss" anywhere on the body; or
- •The medical records document a notation of "hair thinning" in a diffuse frontal or female pattern.

Group 3, Symptom 9: Unacceptable Proof for Alopecia

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

- Medical records reflect a notation of "thinning" only.
- Hair loss is directly related to other causes or medical conditions.
- A diagnosis of alopecia existed prior to the date of your first breast implantation.

Group 3, Symptom 10: Sustained Balance Disturbances

Balance disturbance can be feelings of dizziness, faintness, lightheadedness, and unsteadiness.

To receive credit for sustained balance, your file must document **ONE** of the following:

- •The QMD or medical records gives a diagnosis of "sustained, chronic or persistent balance problems"; **or**
- The file documents continuing complaints of dizziness, lightheadedness, unsteadiness, ataxia or vertigo for at least 60 days or more.
- •A positive Romberg or inability to tandem walk found on physical examfor at least 60 days or more.

Group 3, Symptom 10: Unacceptable Proof for Sustained balance disturbances

Common reasons why claimants receive a deficiency notice about the symptom of Sustained Balance Disturbances:

- The medical records do not establish complaints or a history of balance disturbance as a continuing problem for at least 60 days.
- The file reflects only <u>one</u> notation of a balance disturbance.
- Balance disturbance is directly related to another cause or medical condition.
- Sustained balance disturbances existed prior to the date of your first breast implantation.

Group 3, Symptom 11: Documented sleep disturbances

The symptom of Documented Sleep Disturbances can be credited if the file documents any **ONE** of the following:

- The history or complaint of trouble sleeping is related to a credited ACTD symptom; or
- The medical records reflect at least two complaints of trouble sleeping; or
- The medical records reflect a history of sleep disturbance over an extended period of time; **or**
- The medical records provide a detailed description of the claimant's trouble falling asleep and/or interruption of sleep; or
- The medical records reflect multiple complaints of insomnia.

Group 3, Symptom 11: Unacceptable Proof for Documented sleep disturbances

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

- The medical records directly relate sleep disturbance to another cause or medical condition.
- The medical records reflect a history of sleep disturbance without a specific cause prior to the date of your first breast implantation.
- The medical records reflect prescriptions for sleeping aids without complaints of sleep disturbances.
- The medical records do not provide a detailed description of sleep disturbance.
- The medical records reflect only one complaint of insomnia or trouble sleeping.

Group 3, Symptom 12: Easy Bruisability or Bleed Disorder

The symptom of Easy Bruisability or Bleeding Disorders can be credited if the file documents any **ONE** of the following:

- The medical records reflect a diagnosis of "Easy Bruisability"; or
- The medical records reflect a diagnosis of "Bleeding Disorders"; or
- The medical records reflect a history of <u>abnormal</u> menstruation involving heavy bleeding that is not related to any gynecological diagnosis; **or**
- The medical records reflect a history of recurring nose bleeds; or
- Abnormal Prothrombin (PT) or Partial Thromboplastin (PTT) laboratory results in the absence of taking anticoagulants such as: heparin, coumadin, and other drugs such as: aspirin, ibuprofen etc. Complaints of easy bruising or notations of large bruises due to unknown causes; or
- Multiple bruises found on physical examination.

Group 3, Symptom 12: Unacceptable Proof for Easy Bruisability or Bleeding Disorder

Common reasons why claimants receive a deficiency notice for the symptom of Easy Bruisability or Bleeding Disorders:

- The physician quotes settlement language stating "Easy Bruisability or Bleeding Disorders" without an explanation as to which symptom you are experiencing.
- Medical records reflect abnormal menstruation without indicating the degree of bleeding.
- Abnormal Prothrombin and/or Partial Thromboplastin results are directly related to another cause or condition.
- •The medical records reflect only one notation of nose bleed.
- •Abnormal bleeding is directly related to gynecological conditions.
- •The medical records directly relate easy bruising or bleeding disorders to another cause or condition.
- •The diagnosis of easy bruising or bleeding disorders existed prior to the date of your first breast implantation.

Group 3, Symptom 13: Chronic Cystitis or Bladder Irritability

Cystitis is inflammation of the bladder.

To receive credit for Chronic Cystitis or Bladder Irritability, your file must document **ONE** of the following:

- Medical records document a diagnosis of "Chronic Cystitis"; or
- Medical records document a diagnosis of "Chronic Bladder Irritability"; or
- Medical records document that <u>ONE</u> of the following symptoms persisted for 60 days or more:
 - Hematuria (blood in urine); or
 - Frequent burning; or
 - Urgency; or
 - Recurring urinary tract infections.

Group 3, Symptom 13: Unacceptable Proof for Chronic Cystitis or Bladder Irritability

Common reasons why claimants receive a deficiency notice about the symptom of Chronic Cystitis or Bladder Irritability:

- •The physician quotes settlement language stating "Chronic Cystitis or Bladder Irritability" without an explanation as to which symptom you are experiencing.
- Cystitis or Bladder Irritability cannot be established as "chronic".
- Complaints of hematuria, burning, urgency or urinary tract infections did not exist for 60 days or more.
- A diagnosis of chronic cystitis or bladder irritability existed prior to the date of your first breast implantation.
- •Chronic cystitis or bladder irritability is directly related to other causes or conditions.

Group 3, Symptom 14: Colitis or Bowel Irritability

Colitis is inflammation of the large intestine that has clinical signs including diarrhea and abdominal pain.

To receive credit for Colitis, your file must document **ONE** of the following:

- The medical records document a diagnosis of Colitis; or
- The medical records document a diagnosis of Bowel Irritability; or
- The medical records document <u>variations</u> of diarrhea, constipation, bloating and/ or cramping; <u>or</u>
- The medical records document any one the following diagnosis:
 - Diverticulitis
 - Diverticulosis
 - Crohn's Disease
 - Spastic Colon
 - Irritable Bowel Syndrome

Group 3, Symptom 14: Unacceptable Proof for Colitis or Bowel Irritability

Common reasons why claimants receive a deficiency notice about the symptom of Colitis or Bowel Irritability:

- The physician quotes settlement language stating "colitis <u>or</u> bowel irritability" without further explanation as to which symptom you are experiencing.
- The medical records reflect a history or complaint of constipation, diarrhea, cramping or bloating alone, but no variation in symptoms noted.
- Colitis or Bowel Irritability is directly related to other causes or medical conditions
- •A diagnosis of <u>either</u> Colitis or Bowel Irritability existed prior to the date of your first breast implantation.

Group 3, Symptom 15: Persistent Low Grade Fever or Night Sweats

Persistent Low Grade Fevers or Night Sweats are defined as fevers or night sweats that last for 60 days or more.

To receive credit for Persistent Low Grade Fevers or Night sweats, your file must document **ONE** of the following:

- The QMD or medical records give a diagnosis of "persistent low grade"; or
- The QMD or medical records give a diagnosis of "persistent night sweats"; or
- The medical records document low grade fevers from 99-100.9 degrees for 60 days or more;
- The medical records reflect complaints of night sweats persisting for 60 days or more.

Group 3, Symptom 15: Unacceptable Proof for Persistent Low Grade Fever of Night Sweats

Common reasons why claimants receive a deficiency notice about the symptom of Persistent Low Grade Fevers or Night Sweats:

- The physician quotes settlement language stating "Persistent Low Grade Fevers or Night Sweats" without further explanation as to which symptom you are experiencing.
- The medical records do not establish fevers or night sweats as a continuing problem lasting for at least 60 days.
- The medical records directly relate night sweats to another cause or medical condition.
- The medical records directly relate fevers to another cause or medical condition.
- •A diagnosis of either persistent low grade fevers or night sweats existed prior to the date of your first breast implantation.

Group 3, Symptom 16: Mucosal Ulcers confirmed by physician

The symptom of Mucosal Ulcers can be credited if the file documents any **ONE** of the following:

- Mucosal ulcers found on physical exam; or
- Mucosal ulcers found on a diagnostic test.

Group 3, Symptom 16: Unacceptable Proof for Mucosal Ulcers

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

- Medical records document ulcers by history only but not on physical exam.
- Medical records directly relate ulcers to another cause or medical condition.
- •Mucosal ulcers are found in the same place pre-implant and post implantation.

Group 3, Symptom 17: Burning Pain in Chest, Breast, Arms, Axilla or Loss of function due to Disfigurement

To receive credit for Breast Complications, your file must document **ONE** of the following:

- The medical records document a complaint(s) of <u>burning</u> breast pain; <u>or</u>
- •The medical records document complications such as contractures, capsulectomies, repeated capsulotomies, rupture and/or breast infections.
- The medical records document a loss of breast function such as tissue loss, scarring, sloughing, necrosis, decreased or loss of sensation in the breast.

Group 3, Symptom 17: Unacceptable Proof for Burning Pain in Chest, Breast, Arms, Axilla or Loss of function due to Disfigurement

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

- Complaints of breast pain are not described as "burning".
- The breast pain is related to other causes or medical conditions.
- The breast complications are related to other causes or medical conditions.

Group 3, Symptom 18: Pathological findings

The symptom of Pathological Findings can be credited if the file documents any **ONE** of the following:

- •The pathology report, QMD letter, or medical records document findings of chronic inflammation, histiocytes, macrophages, giant cells, foreign bodies or siliconomas; **or**
- Microscopic report, QMD letter, breast cultures or other pathology reports confirms a breast infection;
- Medical records reflect treatment of a breast infection.

Group 3, Symptom 18: Unacceptable Proof for Pathological Findings

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

- •The claimant received silicone injections prior to the <u>first</u> breast implantation.
- •Pathological findings, QMD letter or medical records do not document any of the following results: chronic inflammation, histiocytes, macrophages, giant cells, foreign bodies or siliconomas.
- •Microscopic report, QMD letter, breast cultures or other pathology reports do not document a breast infection.

ACTD Compensation

Disease Option I

What are the levels of compensation for ACTD?

- Disability Level A \$50,000 Death or Total Disability
- Disability Level B \$20,000 An individual shall be considered 35% disabled if she demonstrates a loss of functional capacity which renders her unable to perform some of her usual activities of vocation, avocation and/or self-care or she can perform them only with regular or recurring severe pain.
- Disability Level C − \$10,000 − An individual shall be considered 20% disabled if she demonstrates a loss of functional capacity which renders her unable to perform some of her usual activities of vocation, avocation and/or self-care or she can perform them only with regular or recurring moderate pain.

The compensation amounts for approved ACTD claims are based solely on the claimant's level of disability.

Premium Payments for ACTD

If Premium Payments are approved by the District Court, approved ACTD claimants could receive an <u>additional</u> 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 – Premium Payment of up to \$2,000 (Class 5)

QMD Statements on Disability

If your file contains more than one QMD letter, the letter with the latest date will be used to determine your disability level, this letter reflects your most current disability status.

Example: Your file contains three (3) QMD letters with the following information: In 1994 the QMD assigned Level B, in 1999 the QMD assigned Level A, in 2000 the QMD assigned Level C. The Level C assignment will be used to determine your current disability status.

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 <u>ONE</u> of the following:

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

Level A Total Disability: Vocation and Self-Care

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

- The physician can describe your limitations in performing both your vocation <u>and</u> self-care activities; **or**
- The physician can simply state "Level A" disability and describe your 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 <u>only</u> the most current letter states that you are now totally disabled, then you must submit <u>the medical records supporting the most current disability letter</u> 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.

Level A Total Disability: Vocation

To be considered totally disabled in your <u>vocation</u>, 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; or
- 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-DCT cannot approve your claim for level A total disability. Your ability to adequately and regularly perform your homemaking activities <u>conflict</u> with the description of your inability to perform your vocation and self-care.

Example: Ms. Jones is unable 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.

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.)

Examples of an approved ACTD Total Disability Level A Claim:

- •Example 1: Claimant Jones, a homemaker, had breast implantation in 1976. Medical records from 1979 reflect that she had **joint pain** and **fatigue that lasted for three months**. Medical records from 1984 reflect that she had **dry eyes** and **muscle pain**. Her implants were removed in 1985 and the pathology report showed **chronic inflammation**. Records dated from 1994 reflect that Ms. Jones required assistance from family members to cook, clean, vacuum and grocery shop due to her joint pain, fatigue and muscle pain. Her daughter must assist with dressing and undressing, must take her to and from the toilet and assist her with getting on and off the toilet due to muscle pain in the legs and joint pain in the hands. All of her grooming is done by her daughter such as combing, brushing and blow drying her hair because she cannot lift her arms above her head to do these tasks by herself due to her severe shoulder pain.
- •Example 2: Claimant Smith was implanted in 1985. She submitted a QMD letter from a Rheumatologist that noted that the Rheumatologist had reviewed Ms. Smith's medical records and found the following: **Polyarthritis** and **K-Sicca**. The letter also noted that Ms. Smith had to quit her job as a hair dresser because she was not able to stand for long periods of time due to pain in her ankle and feet joints from her polyarthritis, or raise her arms to cut or groom hair due to hand and wrist pain, and noted that her husband had to assist her to dress and undress and to bathe because she could not do these tasks by herself because of her painful finger and wrist joints from her Polyarthritis.

Note: Your claim can be approved for a level of disability; however, the SF-DCT cannot pay a disease claim until you qualify for both disease and a level of disability.

ACTD Level A Total Disability – Unacceptable Proof

The following are <u>unacceptable</u> examples of Level A 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 <u>ineligible</u> 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 actively 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. (Example: The QMD states that you are unable to work because of fatigue but you were not credited with the symptom of chronic fatigue.)
- •If your file mentions homemaking then in order to qualify the records must reflect that you have difficulty performing this activity. (See example on page 144)
- The file does not provide any details or descriptions about your inability to perform both vocation and self-care.

ACTD Level A Total Disability – unacceptable proof continued

- The QMD increases your disability rank to level A total disability, but he or she does not perform a <u>new examination</u> or provide <u>current medical records</u> to support the new level assigned. The new disability rank cannot be based solely on a phone call with you or a review of a questionnaire that you have completed.
- The QMD describes severe limitations or an inability to dress, feed, groom and/or toilet yourself alone but the <u>same</u> physician or your medical records indicate that you are working full time.
- The file reflects detailed descriptions about your inability to perform vocation (job or homemaking) because of an approved ACTD symptom or condition, but it does not contain information about your self-care limitations.
- The file reflects conflicting information regarding either your vocation and/or self-care limitation. (Example: file reflects that you are either working or able to perform all or most of your self-care activities.)

ACTD Level A Total Disability – Assisted Living Home

Level A can be approved when a claimant's condition has deteriorated to the point that she is now in an assisted living home or requires 24-hour care due to ACTD or one of the credited symptoms or conditions.

Note: To ensure approval of your claim, it is best to submit <u>all</u> medical records available to support the statement.

ACTD Disability Level B - \$20,000 (U.S.) (Class 5)

There are two ways to approve an ACTD level B disability claim:

- 1. Your file <u>must</u> provide an adequate description of your functional limitations (difficulty or inability) to perform vocation, avocation and/or self-care activities due to a credited ACTD symptom; <u>or</u>
- 3. Your file <u>must</u> provide sufficient documentation that you have regular or recurring severe pain due to a credited ACTD symptom.

Requirements for Disability Level B based on treatment of Severe Pain

To approve Level B disability based on severe pain, your file must document that the pain is severe <u>and</u> regular or recurring. This means that your file must reflect <u>more than one complaint</u> of pain in a credited location <u>and</u> the pain must be established as regular or recurring. Below are some examples of acceptable documentation that may establish your pain as severe:

Medications

- 1. Narcotics
- 2. Demerol
- 3. Lortab
- 4. Lidocaine Injection
- 5. Depo Medrol Injection
- 6. Voltaren
- 7. Duragesic patch
- 8. Darvocet

Treatments

- 1. Physical therapy
- 2. Acupuncture
- 3. Epidural blocks
- 4. Traction
- 5. Massages
- 6. Chiropractor

Note: The medication and treatment <u>must</u> be prescribed for your credited ACTD pain symptoms.

Requirements for Level B Disability Based on complaints of Severe Pain (continued)

Additional examples of acceptable ways to document Level B disability:

- 1. Complaints or history of unbearable pain.
- 3. Complaints or history of stabbing pain.
- 5. Complaints or history of excruciating pain.
- 7. Complaints or history of sharp or shooting pain.
- 5. Complaints or history of severe pain.
- 7. Complaints or history of intolerable pain.
- 9. Complaints or history of debilitating pain.

Note: If the physician quotes settlement language to describe your severe pain, your file **must** contain documentation to support the physician's statement. The documentation can include medications prescribed to treat your severe pain, verbal complaints of severe pain or certain treatments prescribed to control your pain.

ACTD Level B – Unacceptable Proof

- The file does not reflect recurring severe pain from one of the following: complaints, medications or treatments.
- The file does not provide an adequate description of at least <u>two</u> of the three activities of vocation, avocation and/or self-care limited by a credited ACTD symptom.
- The QMD based your disability on severe pain from an ineligible condition or symptom.
- The QMD based disability on severe pain but the pain cannot be established as recurring.
- The treating doctor or QMD increases your disability rank to Level B disability but he or she does not perform a <u>new examination</u> or provide <u>current medical records</u> to support the new level assigned. The new disability rank cannot be based solely on a phone call with you or a review of a questionnaire that you completed.

ACTD Level B – Unacceptable Proof continued

- The QMD or treating doctor assigns Level B disability but your pain is described as "moderate."
- The QMD or treating doctor based your disability on severe pain but you were not credited with any pain symptoms.
- Your file supports severe pain, but there is no disability assignment from a QMD or treating physician in the file.
- The treating doctor or QMD letter describes your limitations in performing your activities of vocation, avocation and/or self-care, but your medical records or QMD letter dated within the <u>same</u> time frame indicate that you are very active.
- The treating doctor or QMD bases your disability on a pre-existing symptom or condition.

ACTD Disability Level C - \$10,000 (U.S.) (Class 5)

There are two ways to approve an ACTD Level C disability claim:

- 1. Your file <u>must</u> provide an adequate description of your functional limitations (difficulty or inability) to perform vocation or avocation or self-care activities due to a credited ACTD symptom; <u>or</u>
- 3. Your file <u>must</u> provide sufficient documentation that you have regular or recurring moderate pain due to a credited ACTD symptom.

ACTD Disability Level C – Establishing Functional Limitation

One way to establish a Level C disability is based on a claimant's <u>functional</u> <u>limitations</u>. To receive credit, your file <u>must</u> provide adequate documentation of <u>ONE</u> of the following:

- 1. An adequate description (example) of at least <u>one</u> activity that you have difficulty or are unable to perform in the areas of vocation, avocation or self care.
- 2. An adequate description (examples) of at least <u>two</u> daily living activities that you are unable to perform such as climbing stairs, writing, driving or riding in a car, bending, sitting, etc.

ACTD Disability Level C – Establishing Disability Based on Pain

The second way to establish a Level C disability is based on complaints of pain. To receive credit, your file must document **MORE THAN ONE** complaint of pain in a <u>credited</u> location and the pain must be established as regular or recurring. Below are some acceptable examples of recurring pain:

- 1. Recurring complaints of burning breast pain
- 2. Recurring complaints of joint pain in a specific area.
- 3. Recurring complaints of muscle pain in a specific area.

Note: Level C disability does not require that the degree of pain be specified in the medical records. Any credited symptom that causes repeated complaints of pain can be approved.

ACTD Level C – Unacceptable Proof

- The QMD or treating physician assigns Level C but the file does not reflect <u>any</u> recurring pain.
- The QMD or treating physician assigns Level C but the file does not reflect limitations in vocation, avocation, or self-care.
- The QMD or treating physician assigns Level C but the file does not reflect two daily living activities affected by a credited symptom.
- You were not credited with any pain symptoms.
- The QMD letter or medical records describe your pain as "mild," "slight" or "minimal."
- The file reflects multiple complaints of pain that are recurring but there is <u>no</u> disability determination in the file from a QMD or treating physician.
- The QMD or treating doctor base your disability on a pre-existing symptom or condition.

Note: The SF-DCT will take under consideration the <u>possibility</u> of approving a claim for Level C disability without a disability statement, if the file reflects the following:

- Complaints of regular or recurring pain due to a <u>credited</u> ACTD symptom not described as slight or mild; <u>or</u>
- Difficulty performing at least one activity in either vocation, avocation or self-care due to a <u>credited</u> ACTD symptom; <u>and</u>
- A detailed description of the attempts made to obtain a disability statement and the reasons why the disability statement is not available.