DISEASE CLAIMANT INFORMATION GUIDE

DOW CORNING FOREIGN BREAST IMPLANT CLAIMANTS
(CLASS 6.1)

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A note about the use of capitalized terms in this Claimant Information Guide:

When you see capitalized terms that are not otherwise defined, they have the meaning assigned to them in the following documents in the following order:

1. **Amended Joint Plan**
2. **Amended Disclosure Statement**
3. **Dow Corning Settlement Program and Claims Resolution Procedures**
4. **Funding Payment Agreement**
5. **DCC Litigation Facility, Inc. Agreement (this document and the preceding ones in this list are collectively referred to as the "Plan Documents")**
6. **Bankruptcy Code**

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This “Claimant Information Guide” was produced by the office of the Settlement Facility-Dow Corning Trust. The information contained in this Claimant Information Guide is intended to summarize the information contained in the Plan Documents. Any conflicts between the information in this Claimant Information Guide shall be controlled by the provisions in the Plan Documents in the order reflected on the cover sheet.

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This "Disease Claimant Information Guide" provides information about the criteria for receiving a Disease Payment. Please use only these materials when you complete your Claim Form (the red edge).

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SECTION 1 – ELIGIBLE DISEASES AND GUIDELINES FOR PAYMENT

Q1-1. What is the Disease Payment Option?

The Disease Payment Option provides payments ranging from $7,200-$180,000 (U.S.) (including a Premium Payment) if you submit medical records and documents that show that you have one (1) of the diseases or conditions in Disease Option 1 or Disease Option 2 as listed in Q1-2. *(Read the Claimant Information Guide for more information about Base and Premium Payments.)*

Q1-2. What are the eligible diseases and conditions?

Eligible diseases and conditions in Disease Option 1 are:

Atypical Connective Tissue Disease (ACTD)
Atypical Neurological Disease Syndrome (ANDS)
Primary Sjogren's Syndrome (PSS)
Mixed Connective Tissue Disease (MCTD)/Overlap Syndrome
Systemic Sclerosis/Scleroderma (SS)
Systemic Lupus Erythematosus (SLE)
Polymyositis (PM)
Dermatomyositis (DM)

Eligible diseases and conditions in Disease Option 2 are:

Systemic Sclerosis/Scleroderma (SS)
Systemic Lupus Erythematosus (SLE)
Polymyositis (PM)
Dermatomyositis (DM)
General Connective Tissue Symptoms (GCTS)

Q1-3. What is the difference between Disease Option 1 and Disease Option 2?

Disease Option 1 uses the same medical criteria and definitions that were used in the original global settlement. If you are familiar with the Revised Settlement Program (RSP), these same criteria were also used in the Fixed Amount Benefit Schedule. Eligible diseases include both classic and atypical presentations of the rheumatic diseases listed in Q1-2. Disease Option 1 also includes two (2) conditions - Atypical Neurological Disease Syndrome (ANDS) and Atypical Connective Tissue Disease (ACTD). You must document a disability or severity that is related to your compensable disease or condition.

The diseases and conditions in Disease Option 2 were not part of the original global settlement. They were defined in the RSP and were contained in the "Long Term Benefit Schedule." In general, the medical criteria to qualify for a Disease Option 2 claim are more restrictive and require more medical documentation and laboratory testing than those in Disease Option 1. You must document a disability or severity level that is related to your compensable disease or condition. The payments for Disease Option 2 are higher than the payments for Disease Option 1. *(Read Q1-4 for more information on the payment amounts.)*

Q1-4. What are the payment amounts for approved disease claims in Disease Option 1 and Disease Option 2?

Disease Option 1 Payments are determined by the disability or severity level of your approved disease or condition.

DISEASE OPTION 1 PAYMENT AMOUNTS

Any approved disease in Disease Option 1 with a Severity or Disability Level of A, B, C or D	You must have proof that you have or had a Dow Corning breast implant and have not had a Bristol, Baxter or 3M silicone gel breast implant**		
	Base Payment	+ Premium Payment	= Total Payment
Severity / Disability Level A	$30,000 (U.S.)	+ $6,000 (U.S.)	= $36,000 (U.S.)
Severity / Disability Level B	$12,000 (U.S.)	+ $2,400 (U.S.)	= $14,400 (U.S.)
Severity / Disability Level C or D	$ 6,000 (U.S.)	+ $1,200 (U.S.)	= $ 7,200 (U.S.)

** If you have acceptable proof that you have or had a Bristol, Baxter or 3M silicone gel breast implant, the Total Payment Amount will be reduced by 50%.

Disease Option 2 Payments are determined by the severity level of your approved disease or condition.

DISEASE OPTION 2 PAYMENT AMOUNTS

Locate your approved disease or condition in Disease Option 2 below and the Severity Level of that disease or condition	You must have proof that you have or had a Dow Corning breast implant and have not had a Bristol, Baxter or 3M silicone gel breast implant**		
	Base Payment	+ Premium Payment	= Total Payment
Scleroderma (SS) or Lupus (SLE); Severity Level A	$150,000 (U.S.)	+ $ 30,000 (U.S.)	= $180,000 (U.S.)
Scleroderma (SS) or Lupus (SLE); Severity Level B	$120,000 (U.S.)	+ $ 24,000 (U.S.)	= $144,000 (U.S.)
Scleroderma (SS) or Lupus (SLE); Severity Level C	$ 90,000 (U.S.)	+$ 18,000 (U.S.)	= $108,000 (U.S.)
Polymyositis (PM) or Dermatomyositis (DM) (there is only one severity level for PM and DM); General Connective Tissue Symptoms (GCTS), Severity Level A	$ 66,000 (U.S.)	+ $ 13,200 (U.S.)	= $79,200 (U.S.)
General Connective Tissue Symptoms (GCTS); Severity Level B	$ 45,000 (U.S.)	+ $ 9,000 (U.S.)	= $54,000 (U.S.)

** If you have acceptable proof that you have or had a Bristol, Baxter or 3M silicone gel breast implant, the Total Payment Amount will be reduced by 50%.

Q1-5. When should I submit my claim for the Disease Payment?

Complete and submit your Disease Payment Claim Form (the red edge) and medical records *only* after you:

1. Complete and return the Proof of Manufacturer Form (the blue edge) and submit the medical records or documents that show that you were implanted with a Dow Corning breast implant. *(Read the Proof of Manufacturer Form Instructions and Section 5 in the Claimant Information Guide for more information.)*; and

2. Obtain all of the medical records and statements necessary to support your claim for an eligible disease or condition and a related disability or severity level. *(Review this Guide and Tab 1 for the medical criteria and documents you will need.)* Do not send your medical records to the Settlement Facility in a piecemeal fashion. Once a disease claim is received, the Settlement Facility will review and evaluate your claim based on the medical records in your file at that time. If you have not submitted all of the necessary records, a letter notifying you of a problem with your claim will be sent. You will have only one (1) year from the date of the letter to correct the problem. *(Read Q8-1 for more information.)*

Q1-6. Why do I have to submit the Proof of Manufacturer Form first?

Your claim for a Disease Payment will be reviewed only after the Settlement Facility determines that you have submitted acceptable proof that you were implanted with a Dow Corning breast implant (or your proof has only a "minor deficiency" as defined in Q5-12 in the Claimant Information Guide). If your proof of manufacturer is not acceptable, then your disease claim will not be reviewed.

Q1-7. What are the definitions for the disability or severity criteria?

The criteria needed to support a disability or severity claim are listed at Tab 1. Read these carefully. Each disease or condition has its own disability or severity criteria.

Q1-8. Some diseases, such as Scleroderma (SS) and Lupus (SLE) are listed under both Disease Option 1 and Disease Option 2. Do they have the same criteria? Why are they listed under both Options?

Four (4) diseases are listed in both Disease Option 1 and Disease Option 2. They are Scleroderma (SS), Systemic Lupus Erythematosus (SLE), Polymyositis (PM), and Dermatomyositis (DM). The disease criteria are similar, but the criteria for the disability or severity level are different under each Disease Option. If you apply for one (1) of these four (4) diseases, the Settlement Facility will evaluate your claim under both Disease Options 1 and 2 to determine if you qualify for payment.

Q1-9. What are the criteria for a disability statement for ANDS or ACTD in Disease Option 1?

The payment amounts for ANDS and ACTD are based on the degree to which you are "disabled" by the condition in question, as determined by your treating physician or "Qualified Medical Doctor" (QMD) in accordance with the following guidelines. *(Read Q4-3 for a definition of a treating physician and Q4-4 for a definition of a QMD.):*

1. The determination of disability will be based on the cumulative effect of the symptoms on the claimant's ability to perform her vocational, avocational, or usual self-care activities.

2. Vocational means activities associated with work, school and homemaking.

3. Avocational means activities associated with recreation and leisure.

4. Usual self-care means activities associated with dressing, feeding, bathing, grooming, and toileting.

5. In evaluating the effect of your symptoms, the treating physician or QMD must take into account the level of pain and fatigue resulting from the symptoms.

6. The disability percentages for Levels "A," "B," and "C" *(described at Q1-10 through Q1-12)* are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the treating physician or QMD in the exercise of his or her professional judgment.

Q1-10. What is the definition of Level "A" disability for ANDS and ACTD in Disease Option 1?

Read the criteria for ANDS and ACTD disability level "A" at Tab 1.

You are eligible for Level "A" disability for death or total disability resulting from your compensable disease or condition. You will be considered totally disabled if you demonstrate a functional capacity adequate to consistently perform none or only a few of your usual duties or activities of vocation or self-care.

In preparing a claim for a Level "A" disability, be aware that the definition of this assigned disability level is a difficult one to meet. You must be unable to do any of your normal activities or only able to do very few of them. Disability Level "A" claims will be reviewed to determine if there is a sufficient description of your daily life and limitations to determine that you meet this strict definition of total disability. It must also be clear in your submission that your total disability is due to the symptoms of your disease or condition and not to other medical conditions or injuries.

If your QMD determines that the death or total disability is clearly and specifically caused by a disease or occurrence other than the compensable disease or condition, the Level "A" disability determination will not be approved.

Q1-11. What is the definition of Level "B" disability for ANDS and ACTD in Disease Option 1?

Read the criteria for ANDS and ACTD disability level "B" at Tab 1.

You will be eligible for Level "B" disability if you are 35% disabled due to the compensable disease or condition. You shall be considered 35% disabled if you demonstrate a loss of functional capacity that renders you unable to perform some of your usual activities of vocation, avocation, and self-care, or if you can perform them only with regular or recurring severe pain.

Level "B" disability claims must be based on severe pain or an inability to do certain activities. If Level "B" is based on pain, there must be pain-producing symptoms that result in severe pain on a regular or recurring basis. Generalized statements about "severe pain" may not be enough. We must be able to verify that the credited ANDS or ACTD symptoms themselves are the cause of the severe pain. If the Level "B" disability is based on limitations on your activities, your submission must provide information concerning the activities that are limited. A conclusory statement, with no information about you or your limitations, will result in a deficiency being assigned. The disability assessment must demonstrate a connection between the symptoms and the specific activities that you can no longer perform. The disability must be due to the compensable disease or condition. The Settlement Facility must have enough information about what the limitations are and the cause of those limitations to be able to verify that your condition meets the requirements for a Level "B" disability.

Q1-12. What is the definition of Level "C" disability for ANDS and ACTD in Disease Option 1?

Read the criteria for ANDS and ACTD disability level "C" at Tab 1.

You are eligible for Level "C" disability if you are 20% disabled due to the compensable disease or condition. You shall be considered 20% disabled if you can perform some of your usual activities of vocation, avocation, and self-care with only regular or recurring moderate pain.

If your submission describes your pain as being only "mild" or "slight," your disability determination will not be approved.

Q1-13. What is the deadline to file a claim for Disease Option 1 or Disease Option 2?

You must complete and submit the Disease Payment Claim Form (the red edge) and supporting medical records on or before fifteen (15) years after the Effective Date. *(Read the Claimant Information Guide for more information about the Effective Date.)*

Q1-14. Why do the charts in Q1-4 above mention Bristol, Baxter and 3M silicone gel breast implants?

If in addition to your Dow Corning breast implant you also have acceptable proof of implantation of a silicone gel breast implant from Bristol, Baxter, or 3M, then your approved Disease Payment will be reduced by 50%. This is known as the "Multiple Manufacturer Reduction."

Q1-15. If I had acceptable proof of a silicone gel breast implant from Bristol, Baxter or 3M in the RSP or FSP but I did not recover any money, will my disease payment in the Settlement Facility still be reduced by 50%?

Yes. If you have questions about whether your Baxter, Bristol or 3M implant is silicone or saline, call Claims Assistance Toll Free at (866) 874-6099.

Q1-16. If I had acceptable proof of a silicone gel breast implant from Mentor and Cox-Uphoff, will my disease payment here be reduced by 50%?

No. The Multiple Manufacturer Reduction only applies if you have acceptable proof of implantation of a Bristol, Baxter or 3M silicone gel breast implant in the RSP.

Q1-17. If I receive a Disease Payment now and then become more ill in the future, can I apply for an additional payment?

Yes, under certain conditions. Read about the increased severity payment for Disease Option 1 and Disease Option 2 in Section 6.

SECTION 2 – ELIGIBILITY GUIDELINES FOR DISEASE PAYMENT CLAIMS

Q2-1. Is there a distinction between "current claimants" and "other registrants" like there was in the Revised Settlement Program (RSP) and Foreign Settlement Program (FSP)?

No.

Q2-2. What types of Dow Corning breast implants are eligible for a Disease Payment? Are saline and silicone gel breast implants both eligible?

Yes, both saline and silicone gel breast implants are eligible. As long as you were implanted with a Dow Corning breast implant, then you are eligible to apply for a Disease Payment.

Q2-3. If I apply for a Disease Payment, can I also apply for other settlement payments?

Yes. Assuming you qualify, you can also receive payment for Explant and Rupture.

Q2-4. Can I apply for both a Disease Payment and the $1,200 (U.S.) Expedited Release Payment?

No.

Q2-5. Do I have to have my Dow Corning breast implants removed to be eligible for a Disease Payment?

No.

Q2-6. Do I have to have an approved disease claim to also apply for the Rupture Payment?

No.

SECTION 3 – HOW TO APPLY FOR A DISEASE PAYMENT

Q3-1. Do I have to choose between Disease Option 1 and Disease Option 2 when I apply for a Disease Payment?

No. Simply check the box on the Claim Form indicating the disease or condition that you want to be evaluated for and submit supporting medical records for that disease or condition and a related disability or severity level.

Q3-2. If I receive a Disease Option 1 Payment, can I later receive payment for one (1) of the diseases or conditions in Disease Option 2?

No.

Q3-3. My disease is not on the list of eligible diseases or conditions in either Disease Option 1 or Disease Option 2. Can I still apply for a Disease Payment?

No. Not every disease or medical condition is covered by the Disease Option. If you do not have one (1) of the eligible diseases or conditions, then you cannot receive payment for your disease or condition.

Q3-4. I was diagnosed with Fibromyalgia. I don't see this on the list of eligible diseases or conditions in either Disease Option 1 or Disease Option 2. Can I still apply for a Disease Payment?

Fibromyalgia is not an eligible disease, so you cannot receive payment based solely on this diagnosis. Many - if not most - of the symptoms of Fibromyalgia though are listed in the criteria for Atypical Connective Tissue Disease (ACTD).

Q3-5. Can I rely on the medical records that I sent to the MDL Claims Office in Houston years ago, or do I have to resend these documents to the Settlement Facility?

You can rely on the records that you submitted to the MDL Claims Office in Houston, Texas. You do not have to re-submit any records.

Q3-6. I submitted medical records to the MDL Claims Office in 1994. Since that time, my condition has changed and I have new and additional records. Can I send those in and have them considered by the Settlement Facility?

Yes.

Q3-7. Can I get a copy of the medical records and documents that I submit to the Settlement Facility?

Keep a copy of the Claim Forms and documents that you submit. If you did not keep a copy, write or call the Settlement Facility to get a copy. Depending on the number of pages in your file, there may be a minimal copying charge.

Q3-8. I don't know how to and can't afford to get a copy of my medical records. Can the Settlement Facility or Claims Assistance Program obtain copies of my medical records for me?

No. You need to obtain these yourself by calling or writing your doctors and requesting a copy of your medical file.

Q3-9. Is there a particular way that I should organize my medical records? Should I put them in a binder or folder? How should I submit them?

The Settlement Facility does not have any guideline on how your medical records should be organized and submitted. The Settlement Facility will review the substance of each claim, and no extra consideration will be based on packaging. Please do not send any extra copies of the Claim Forms.

Q3-10. The Plan says that if I fail to cure any deficiency in my disease claim within one (1) year, I am barred from re-filing that claim, but I can bring a new disease claim if I have a new compensable condition that shows up after that one-year period. What is a new compensable condition?

The Settlement Facility cannot provide a precise definition. The determination of whether you have a new compensable condition depends on the unique circumstances of each case and medical records.

SECTION 4 – DISEASE OPTION 1 GUIDELINES

Q4-1. I've read the medical criteria for disease and disability at Tab 1. I think I qualify for ACTD. What do I need to submit to support my disease claim under Disease Option 1?

Submit all records that contain information relevant to the criteria for the disease for which you are applying. This includes:

1. Medical records relating to the relevant signs, symptoms, findings and test results for the disease you are applying for; and

2. Medical records showing the severity of your disease or, if applicable, a determination of a disability level by either a Qualified Medical Doctor (QMD) or your treating physician.

Q4-2. Do I need to submit all of my medical records from every doctor I have ever seen?

Submit those medical records or documents that your physician relied upon in arriving at the diagnosis and findings in your QMD statement or diagnosis. It is not possible to define in advance precisely what medical records will be needed by the Settlement Facility in addition to the statement or diagnosis in order to process any particular claim. This will largely depend upon the nature of the examination or review conducted by the doctor and the form and content of the statement or diagnosis.

Your submission might include a patient questionnaire, physical findings obtained from an assistant's notes in the office chart, and certain lab or other test reports. If your doctor needed to review earlier medical records obtained from other physicians to make a definitive statement about your condition or disability, then those records must also be submitted, if available. If your physician has first-hand knowledge of everything that is the basis of his or her opinion based on his/her examination of you, and the statement or diagnosis sets out that knowledge in sufficient detail, it is possible that no additional records will be required.

Q4-3. What is a "treating physician" as that term is used in Q4-1 above?

A "treating physician" is one who has seen, examined, and treated you on several occasions, and not a doctor you have seen only for purposes of getting an evaluation to make a claim under Disease Option 1.

Q4-4. What is a Qualified Medical Doctor or "QMD?"

"Qualified Medical Doctor" is a term used to describe a physician who is Board-certified (not Board-eligible) in internal medicine, rheumatology (a sub-speciality of internal medicine), neurology, neurological surgery, or immunology who prepares the statement or diagnosis that you filed in support of your disease claim.

Q4-5. Is a Qualified Medical Doctor a "Treating physician?"

"Treating physician" includes a Qualified Medical Doctor if that QMD states that (s)he has the information necessary to form a professional opinion about your disability and sets forth in the statement or diagnosis (or a supplemental statement) the information upon which that opinion is based and the source of that information.

Q4-6. What does "Board-certified" mean?

"Board-certified" means certification in a particular medical specialty by the American Board of Medical Specialists. For Foreign Claimants, the Settlement Facility will define standards for equivalent certification in each country. The Settlement Facility has adopted the existing standards of the MDL claims office.

The certification standards defined to date are as follows:

England: Fellows in good standing of the Royal College of Surgeons of England who have been awarded that organization's Certificate of Completion of Specialist Training in Neurosurgery. Also, Fellows in good standing of the Royal College of Physicians of England who have been awarded that organization's Certificate of Completion of Specialist Training in Neurology, General (Internal) Medicine, Immunology, or Rheumatology.

Finland: A postgraduate specialty degree in allergology, immunology, neurosurgery, neurology, internal medicine, or rheumatology from the Universities of Helsinki, Turku, Tampere, Oulu, or Kuopio in Finland.

Germany: Designation of medical specialist in internal medicine, rheumatology, neurosurgery, or neurology, granted by the German Federal Medical Board.

Israel: Physicians licensed by the Department of Medical Professions of the State of Israel to practice as a specialist in internal medicine, immunology, rheumatology, neurology, or neurosurgery.

Norway: Specialist approval by the Norwegian Medical Association in internal medicine, neurology, neurosurgery, or rheumatology.

South Africa: Medical specialists in neurology, neurosurgery, internal medicine, or rheumatology registered with the South African Medical and Dental Council.

Sweden: Specialist approval by the Swedish National Board of Health and Welfare in neurosurgery, internal medicine, allergology, neurology, or rheumatology.

Switzerland: Title of medical specialist granted by FMH Swiss Medical Association in allergology and clinical immunology, internal medicine, neurology, neurosurgery, and rheumatology.

Q4-7. Can a doctor who is "Board-eligible," but not yet Board-certified write my disease diagnosis or statement?

No. Only "Board-certified" physicians can submit the statement or diagnosis. His/her records can, however, be part of the records submitted to allow the Settlement Facility to classify your claim.

Q4-8. Can a doctor of osteopathy (D.O.) be a Qualified Medical Doctor and write my statement or diagnosis?

Yes. D.O.s may also write diagnoses for disease claims as long as they are Board-certified by the same Board that certifies Medical Doctors and that certification is within an appropriate specialty for the disease option for which you are requesting an evaluation.

Q4-9. What are "appropriate" Board-certified specialists for disease claims in Disease Option 1?

Doctors who write a statement or diagnosis of your disease must be Board-certified in an appropriate specialty for your disease claim. What specialty is appropriate depends on the complaints and symptoms you have.

Q4-10. What would be an appropriate speciality for Scleroderma, Lupus, Polymyositis, Dermatomyositis, MCTD, Primary Sjogren's, or ACTD?

These diseases are all rheumatic diseases or conditions. A Board-certified internist or rheumatologist would be an appropriate specialist for any of these diseases. If you want to pursue a disease claim for Scleroderma, Lupus, Polymyositis or Dermatomyositis under Disease Option 2, then you must be personally examined by a Board-certified rheumatologist. A Board-certified internist will not be acceptable for Disease Option 2 claims.

Q4-11. What would be an appropriate specialty for Atypical Neurological Disease Syndrome (ANDS)?

Atypical Neurological Disease Syndrome (ANDS) involves neurological complaints; therefore, a Board-certified neurologist would be an appropriate specialist for ANDS.

Q4-12. Several of the eligible diseases and conditions are clustered together, and the same criteria seem to apply to each (i.e., ACTD/ARS/NAC). When a Qualified Medical Doctor (QMD) is writing my statement or diagnosis of these conditions, what name should (s)he give it? All three (3) or any particular one (1)?

Atypical Connective Tissue Disease (ACTD), Atypical Rheumatic Syndrome (ARS), and Nonspecific Autoimmune Disease (NAC) are listed together because they are sometimes used interchangeably by physicians. Depending on the physician, any one of them may be used to describe the particular mix of symptoms and/or findings that are present in a particular case.

Q4-13. Does my treating physician have to be Board-certified to write the statement or diagnosis for my Disease Option 1 claim?

Yes, (s)he must be Board-certified to write the QMD statement or diagnosis of your disease.

Q4-14. Does my treating physician have to be Board-certified to write my disability statement for my Disease Option 1 claim?

No, (s)he does not have to be Board-certified to write the disability statement.

Q4-15. If my disability criteria is based on the severity of my disease in Disease Option 1 (such as claims for Scleroderma, Lupus, Polymyositis, Dermatomyositis, MCTD/Overlap Syndrome, or Primary Sjogren's Syndrome), what do I have to submit to the Settlement Facility to document my disability?

You must submit all of the medical records that the physician relied upon in making his or her disability determination. This includes, for example, any disability questionnaire that you completed to assist in the physician's determination.

Q4-16. I was in a car accident and was disabled as a result. Can I use that disability rating from my Disease Option 1 claim?

No. Your disability must be related to your compensable condition. The pain must be due to your ACTD or ANDS symptom(s). For example, ACTD symptoms such as alopecia (hair loss), chronic fatigue and loss of breast function normally do not have a pain component. For your ACTD disability to be approved, you must be experiencing pain from at least one (1) of your qualifying symptoms. Also, pre-existing diseases and conditions are not eligible for consideration.

Q4-17. Can my treating physician or QMD write my disease and/or disability statement tracking the language in the disability definition? Will that be sufficient for my claim to be approved?

No. Generalized statements by your QMD that track the disease or disability language cannot replace the responsibility of the Settlement Facility to review, on a detailed level, all of the claim documentation provided.

Q4-18. In several places in the Disease Option 1 criteria, especially in the ACTD criteria, the word "documented" precedes a listed symptom. What does "documented" mean?

It is not possible to give one precise definition of this word, because its meaning often depends on the particular symptom involved. Generally, it means that it is based on some reliable information other than simply the patient's complaint or oral history.

For some symptoms, this means that the physician has verified the condition on physical examination or through a lab test.

For others, primarily those symptoms that are entirely subjective, it can mean that the physician has performed a physical examination and questioned the patient about the complaint sufficiently to be able to form a professional opinion, utilizing all the doctor's knowledge and training, that the complaint is a valid one. (In this situation, it is important that the physician relying on these complaints does not qualify the diagnosis by stating that these "findings" are based solely on the patient's history given at the time of the single visit to the Board-certified specialist. The physician needs to feel comfortable in concluding that the problems do indeed exist.)

"Documented" can also mean that written notations of the symptom are found in the patient's medical records that predate her coming to a physician for purposes of obtaining a statement or diagnosis to submit with her disease claim.

Q4-19. Can I use an official document stating that the Social Security Administration has declared me to be totally disabled to support my claimed disability level?

No. You may only use determinations of disability made by a treating physician or a Qualified Medical Doctor (QMD).

Q4-20. I am not sure if I have lupus or ACTD. The Disease Payment Claim Form says I may pick only one (1) disease. How do I decide which to select?

Consult with your doctor prior to completing the Disease Payment Claim Form about what disease or condition he or she has diagnosed or determined you may have. Check the box that matches your diagnosis and supporting medical records. If you check the box for either lupus, scleroderma, polymyositis, dermatomyositis or GCTS and do not qualify, then the Settlement Facility will review your claim for ACTD and/or ANDS if, in the judgment of the Settlement Facility, it appears that you may qualify for one (1) of these conditions.

SECTION 5 – DISEASE OPTION 2 GUIDELINES

Q5-1. How can I determine if I qualify for a Disease Option 2 Payment?

Review the criteria at Tab 1 and discuss your condition with your physician.

Q5-2. In addition to the medical criteria and severity level documentation required in Disease Option 2, what else am I required to submit or do I have to do in order to qualify for a Disease Option 2 claim?

In addition to the medical criteria and severity level documentation (where applicable), you must also submit or meet the following criteria:

1. You must submit all medical records establishing the required findings or laboratory abnormalities; and
2. Qualifying findings must have occurred within a single 24-month period within the five (5) years immediately preceding the submission of the claim except that this period is tolled from May 15, 1995 to the Effective Date. Findings supplemented in response to a deficiency letter sent by the Settlement Facility do not have to fall within the 24-month period outlined above; and
3. If exclusions are noted for a required finding, the physician making the finding or ordering the test must affirmatively state that those listed exclusions are not present; and
4. The physician recording a GCTS finding or making a disease diagnosis must also affirmatively state that the qualifying symptoms did not exist before the date of first implantation. This statement can be based upon patient history so long as it is consistent with medical records in the physician's possession. Failure to make these affirmative statements will result in a deficiency letter; and
5. All medical records establishing the required findings or laboratory abnormalities must be submitted to the Settlement Facility. In addition, you must supply all underlying office charts, radiology/pathology reports, and tests results in the possession of the physician who makes the required findings or statements, or who ordered the required tests; and
6. QMD statements may be acceptable proof under Disease Option 2 if:
   A. The QMD is a Board-certified rheumatologist - for Lupus, Scleroderma, Polymyositis or Dermatomyositis - or is Board-certified in the appropriate specialty to make the required GCTS findings; and
   B. The statement covered all of the detailed findings that are required in Disease Option 2; and
   C. The QMD personally examined you; and
   D. The QMD included all of the additional statements required concerning listed exclusions and pre-existing symptoms.

In most cases, additional physician statements will have to be submitted for Disease Option 2 claims.

Q5-3. What are the "affirmative statements" and "exclusions" referenced in Q5-2 above?

An affirmative statement is a written statement by the physician stating that the listed exclusion for your diagnosed disease is not present in your case. Exclusions are contained in the "General Guidelines" preface to Disease Option 2 and in bracketed language in each of the Disease Option 2 diseases, and begin with the word "Exclusion:" For example, criterion #5 (arthritis) for SLE contains a bracketed Exclusion of erosive arthritis. If your SLE diagnosis is based on arthritis, the diagnosing rheumatologist must affirmatively state in your medical records or letter that you do not have erosive arthritis.

Q5-4. What Board-certified specialist is required to provide a diagnosis of Scleroderma, Lupus, Polymyositis or Dermatomyositis in Disease Option 2?

To qualify for Scleroderma, Lupus, Polymyositis or Dermatomyositis in Disease Option 2, you must be personally examined and have a diagnosis by a Board-certified rheumatologist.

Q5-5. I was diagnosed with one (1) of the Disease Option 2 diseases (Scleroderma, SLE, Polymyositis or Dermatomyositis), and my medical records contain all of the required findings. Can I rely on this diagnosis even though it was not made by a Board-certified rheumatologist?

No.

Q5-6. My treating rheumatologist (who isn't Board-certified) diagnosed me with one (1) of the Disease Option 2 diseases. Can I submit my medical records along with a Board-certified rheumatologist stating that (s)he has reviewed all of these records and agrees with and confirms my disease diagnosis?

No. A diagnosis by a Board-certified rheumatologist must be based upon his or her personal examination of you. (S)he cannot rely solely on reviewing your medical records to provide the diagnosis required in Disease Option 2.

Q5-7. Does a claim for "General Connective Tissue Symptoms" have to be supported by a diagnosis made by a Board-certified rheumatologist?

No. No diagnosis is required for this category under Disease Option 2.

Q5-8. What do I have to submit to support a claim for GCTS?

Your medical documentation must establish that one (1) of the required combinations of findings from the three (3) groups of findings is present. Some findings can only be made by a particular type of medical specialist. Read the GCTS criteria at Tab 1 carefully.

Q5-9. The general guidelines for Disease Option 2 claims require that qualifying findings must have occurred within a single 24-month period within the five (5) years immediately preceding the submission of the claim. What date is used to determine the date the claim was submitted?

The date can be either the date the Settlement Facility receives the Disease Payment Claim Form (the red edge) or the date your original disease claim form was received by the MDL Claims Office in 1994. We will apply the date that, in your particular situation, allows you to meet this requirement.

Q5-10. I was a current claimant in the RSP, and under that program I could not apply for GCTS initially. Am I allowed to make a claim for GCTS under the Dow Corning Settlement Plan, or do I have to first file a claim for ACTD?

You are permitted to make a claim directly for GCTS.

SECTION 6 – INCREASED SEVERITY PAYMENT FOR DISEASE OPTION 1 AND DISEASE OPTION 2 CLAIMS

Q6-1. If I receive a Disease Payment now but become more ill in the future, can I apply for an additional payment?

Yes. For approved Disease Option 1 claimants, there is an Increased Severity Fund of $15 million (U.S.) (Net Present Value) to pay approved claims. For approved Disease Option 2 claimants, there is also an increased severity payment but there is no specific monetary cap as in Disease Option 1. You can apply for an increased severity payment only in the Disease Option in which you were approved and paid. For example, if you were compensated for ACTD in Disease Option 1, then you can only apply for increased severity benefits in Disease Option 1.

Q6-2. What are the eligibility criteria for the Disease Option 1 Increased Severity Fund?

To be eligible for an increased severity payment under Disease Option 1, you must be able to document that you meet the Level "A" disability criteria for your approved disease.

Q6-3. If I am approved for the Disease Option 1 Increased Severity Fund, how much can I recover?

You will be eligible to receive the difference between your original approved disease payment amount and the Level "A" amount.

Q6-4. My treating physician wrote a statement that my ACTD disability level has increased from Level "C" (20% disabled) to Level "B" (35% disabled). Am I eligible for the Disease Option 1 Increased Severity Fund?

No.

Q6-5. What are the eligibility criteria for the Disease Option 2 increased severity payment?

You may be eligible if you are able to document on or before fifteen (15) years after the Effective Date that you are entitled to a larger payment than previously allowed. You can qualify by either of the following two (2) methods:

1. You are diagnosed with a new eligible disease in Disease Option 2; or
2. Your existing Disease Option 2 disease becomes more severe such that it qualifies you for a higher severity level payment amount.

Q6-6. When and how will approved Disease Option 1 and Disease Option 2 increased severity payments be made?

Disease Option 1 and Option 2 increased severity payments will be paid when and if the District Court authorizes Premium Payments to be made. *(Read Q2-6 in the Claimant Information Guide for more information about Premium Payments.)*

Q6-7. Does the Disease Option 1 Increased Severity Fund allow me to move from Disease Option 1 to Disease Option 2?

No.

SECTION 7 – PROCESSING OF DISEASE CLAIMS AND NOTIFICATION OF STATUS LETTERS

Q7-1. What types of problems or "deficiencies" are there for disease claims? What do they mean, and how can I cure them if my claim is found to be deficient in some way?

A non-exhaustive list of the deficiencies that may appear in your Notification of Status letter is included here, with explanations as well as information concerning how the deficiency might be cured. While it is impossible to anticipate every situation, the Settlement Facility has established certain deficiency standards that will guide the review of disease claims.

A. Documentation Criteria

Deficiency: "The following ACTD symptoms were not documented: *[specific symptoms listed here].*"

Guidelines to cure this Deficiency: Read Q4-18 for a description of the term "documented." This deficiency can be cured by providing (1) proof of verification of your symptom through physical examination, (2) a supplemental statement from your QMD revealing that (s)he questioned you sufficiently about this symptom and concluded that the complaint is valid, or (3) additional medical records reflecting that you complained about this symptom on other occasions.

B. Disability Deficiencies

Deficiency: "All the records on which the QMD based his/her determination of your disability were not submitted with your claim."

Guidelines to cure this Deficiency: Your QMD indicated that (s)he relied on some documents in making your disability determination, but those other documents have not been submitted. Before we can confirm your disability, we must have all the records that the QMD used to make that determination. You can cure this deficiency by filing those documents.

Deficiency: "Information contained in your claim documents indicates that you are not disabled by a compensable condition."

Guidelines to cure this Deficiency: Your medical documentation affirmatively reveals you are not disabled. If this is incorrect, this deficiency can possibly be cured by providing a statement from your QMD or treating physician describing your current disability and providing a satisfactory explanation for the contradictory information submitted earlier.

Deficiency: "Information contained in your claim documents indicates that the disability determination is inconsistent with settlement criteria."

Guidelines to cure this Deficiency: Your QMD or treating physician made a determination of your disability, but information about your pain or limitations on

your activities (either in the QMD's statement or elsewhere in your records) conflicts with the requirements for that disability level. The deficiency can possibly be cured by a statement from your QMD or treating physician assigning a disability level that is appropriate for your condition or providing information about your disability that is consistent with settlement criteria for that level. (If your supplemental documentation provides new information in support of the disability level you originally claimed, please also provide an explanation for the contradictory information submitted earlier.)

Deficiency: "Your claim documents contain insufficient information about your condition to evaluate whether the disability determination is consistent with settlement criteria."

Guidelines to cure this Deficiency: Although your QMD or treating physician made a determination of your disability, there is not enough information in your claim file to allow the Settlement Facility to determine if that disability level was appropriately assigned by the physician. This deficiency can be cured by providing a supplemental statement from your treating physician or QMD describing your level of pain or limitations on your activities. If your disability is caused in part by a disease or condition that is not compensable under the original disease schedule, you can only be approved for the level of your disability that is caused by the covered disease or condition. In that situation, make sure that in describing your disability, your physician clearly indicates the extent of your disability caused by the disease or condition covered by the settlement terms.

Deficiency: "Information contained in your claim documents indicates that you are no longer disabled by a compensable condition."

Guidelines to cure this Deficiency: Your claim documentation clearly indicates that you are no longer suffering from any earlier disability you may have had. This deficiency can only be cured if you are once again disabled. Provide a statement from your QMD or treating physician describing your current disability and explaining the change from your earlier-reported condition.

Deficiency: "Your claim documents did not contain a determination by a treating physician or QMD of your disability."

Guidelines to cure this Deficiency: Your file contained no determination of your disability by either your treating physician or a QMD. If your file did contain a disability determination from a physician, this deficiency was assigned because we were unable to confirm that the physician who made that disability determination was either a treating physician or an appropriate Board-certified specialist. This disability can be cured by obtaining a determination of disability from your treating physician or a physician Board-certified in one of the specialties qualifying as "QMD" specialties.

C. Number of Symptoms

Deficiency: "In addition to the other deficiencies noted in this letter, you need one (1) more symptom to qualify for a compensable condition."

Guidelines to cure this Deficiency: After curing any other symptom-related deficiencies noted in your Notification of Status, you will still need one more symptom to qualify. This deficiency can be cured by providing medical records or a supplemental statement from your QMD reflecting any additional symptoms you have that satisfy settlement criteria.

Deficiency: "In addition to the other deficiencies noted in this letter, you need more than one (1) additional symptom to qualify for a compensable condition."

Guidelines to cure this Deficiency: After curing any other symptom-related deficiencies noted in your Notification of Status, you will still need two (2) or more additional symptoms to qualify for the applicable disease or condition. This deficiency means that your claim documentation contained few (or perhaps none) of the signs, symptoms, and findings required to support a claim for the particular disease or condition mentioned in your Notification of Status. You need to review in detail the exact requirements for establishing your disease or condition. These requirements are found at Tab 1. Look carefully through the claim documentation you submitted to see which, if any, of the signs, symptoms, and findings required by the Disease Schedule at Tab 1 can be found in your documentation. A thorough comparison of these documents should give you the answers you need. The deficiency can be cured by providing medical records or a supplemental statement from your QMD reflecting any additional symptoms you have that meet the criteria for that disease or condition.

D. Pre-Existing Conditions

Deficiency: "The following ACTD symptoms existed before you received your first (1st) breast implant: *(specific symptoms listed here)*."

Guidelines to cure this Deficiency: Your claim records reflect that you suffered from these ACTD symptoms before you had your first (1st) breast implant. The Settlement Facility is not permitted to credit those pre-existing symptoms. The only way this deficiency can be cured is if there are typographical errors in the dates in your records. If there are indeed typographical errors in those dates, you must provide an affirmative statement from the physician whose records contain those errors explaining in detail the nature of those errors and the true dates that should have been reflected in those records.

Deficiency: "Information contained in your claim documents indicates that the compensable condition from which you suffered before your first (1st) implant has not increased in severity or disability since that implant."

Guidelines to cure this Deficiency: Your records show that you suffered from the disease noted on your Notification of Status before you received your first (1st) breast implant. That condition is now compensable only if it increased in severity or in its impact on your disability after implantation. You can cure this deficiency by providing either a supplemental report from your treating physician or QMD that affirmatively reveals that your condition has worsened to the point that you are now in a higher payment category or medical records that demonstrate that increase.

E. Physician Signature

Deficiency: "Your QMD's statement or diagnosis was not signed." "Your QMD's determination of disability or severity level was not signed."

Guidelines to cure this Deficiency: A statement or diagnosis from a QMD must have that physician's signature. You can cure this deficiency by having the QMD sign a copy of the original statement or diagnosis, and filing that signed copy with the Settlement Facility. If the deficiency noted is lack of signature on the disability statement, be sure that the statement which you have the physician sign is the one that contains his or her determination of your disability.

F. Failure to Meet Settlement Criteria

Deficiency: "Your medical records did not reveal whether the following lab tests were performed by the method required by the settlement or if the results of those tests meet settlement criteria: *(specific test listed here).*"

Guidelines to cure this Deficiency: The settlement requires that the lab tests noted be performed by a certain stated method or that the results of those tests meet certain minimum values. If your tests did meet that stated criteria, but your original documentation failed to reveal that fact, you can cure this deficiency by providing a statement from either the lab or the physician who ordered the test reflecting the method by which it was run and the results reported in the value required by the settlement. If your tests did not, in fact, meet the stated criteria, you can cure this deficiency by having them retaken in the manner required by the original disease schedule.

Deficiency: "The following signs and symptoms did not meet settlement criteria: *(specific symptoms listed here).*"

Guidelines to cure this Deficiency: The symptoms noted were not shown in your claim file to meet the criteria that the original disease schedule specifies. Perhaps your complaints were not shown to rise to the level required for us to credit you with that particular symptom. Perhaps the records revealed your complaint fell within a category affirmatively excluded by settlement criteria. This deficiency can be cured by providing either a supplemental statement from your QMD or the medical records demonstrating that your symptom does indeed meet the criteria stated in the original disease schedule.

Q7-2. My Notification of Status says I have a few deficiencies in my ACTD claim. I have recently been diagnosed with Lupus. Can I submit a new claim for Lupus instead of only correcting my ACTD deficiencies?

Yes.

Q7-3. My Notification of Status letter says that "upon cure of appropriate deficiencies" my claim will be approved. What does "appropriate deficiencies" mean?

Certain deficiencies, such as pre-existing ACTD symptoms, are probably not curable, but we provided this information to let you know how these factors were evaluated.

SECTION 8 – DEADLINES

Q8-1. How long do I have to cure any problems identified in my Notification of Status letter?

If there is a problem with your disease claim, the Settlement Facility will inform you of the problem. You will have one (1) year from the date of the letter informing you of the deficiency to correct the problem. If you do not correct the problem within this one (1) year period, then your disease claim will be denied, and you will be limited in the future to applying for a new compensable condition that manifests after the conclusion of the one (1) year period to cure the deficiency.

Because of this short time to correct problems, it is important that you review your medical records carefully before you send them in for review. Do not send your records to the Settlement Facility in a piecemeal fashion. Once a disease claim is received, the Settlement Facility will review and evaluate your claim based on the medical records and documents in your file at that time. If you have not submitted all of your medical records and documents that support your claim, then you will receive a deficiency letter informing you that your claim is being denied.

If your medical records meet the proof requirements in Tab 1, then you will receive a letter from the Settlement Facility informing you that your claim is approved. Approved claims will be paid after the Effective Date.

GLOSSARY OF TERMS

This Glossary of Terms defines some of the terms used in the Claimant Information Guide.

"Case Management Order:"

A written order that was issued by Judge Denise Page Hood of the United States District Court for the Eastern District of Michigan on November 13, 2000. The Case Management Order, also called the "CMO," describes some of the rights and duties of claimants against DCC Litigation Facility, Inc. who wish to litigate – rather than settle – their claims. The Case Management Order can be reviewed at www.dcsettlement.com.

"Class of claimants:"

A grouping of claimants created for purposes of the Amended Joint Plan. The groupings are specified in the Plan. The claimants are divided into Classes based on the types of implants received by claimants and the different countries in which the claimants live, are citizens, or received their implants.

"Deficiency:"

In the Settlement Facility-Dow Corning Trust, a "deficiency" means that the proof submitted does not meet the requirements for the Settlement Facility to approve the claim.

"Effective Date:"

Read Q9-5 of the Claimant Information Guide.

"Explant:"

To remove an implant by surgical procedure.

"Litigation" or "litigate:"

To resolve a dispute through the court system. Litigation involves the filing of a lawsuit in a court before a judge.

"Manifested injury:"

Under the Plan a "manifested injury" means that the claimant has an illness or symptoms of sufficient severity to support a disease payment under either Disease Option 1 or Disease Option 2.

"MDL Claims Office:"

The claims office that is administering the settlement of the claims against implant manufacturers other than Dow Corning. The MDL Claims Office is administering the Revised Settlement Program, also known as the "RSP."

"Operative report:"

A report issued by a doctor about a surgical operation on a person. An operative report may be kept in the records of a doctor or of the hospital or other medical facility at which the surgical operation was performed.

"Original global settlement:"

A class action settlement in 1994 of claims against a group of breast implant manufacturers and suppliers.

"Settlement Facility:"

The entity that administers the settlement of personal injury claims involving Dow Corning products.

"TMJ:"

An abbreviation for "temporo-mandibular joint." The TMJ is the hinge at which a person's lower and upper jaws connect with each other.

TAB I

MEDICAL CONDITIONS AND CHARACTERISTICS OUTLINE OF DEFINITIONS AND CLASSIFICATION CRITERIA

TAB 1
MEDICAL CONDITIONS AND CHARACTERISTICS OUTLINE OF DEFINITIONS AND CLASSIFICATION CRITERIA

PART A. DISEASE AND DISABILITY/SEVERITY DEFINITIONS: DISEASE PAYMENT OPTION 1

GENERAL GUIDELINES

The following are general guidelines, which are adopted from and are intended to be applied consistently with the Revised Settlement Program and interpretations thereof, to be used in the submission and evaluation of a Claim for compensation under Disease Payment Option 1:

There are two (2) ways to document a claim for Disease Payment Option 1 compensation: (a) a Claimant can provide a statement or diagnosis from a physician Board-certified in an appropriate specialty, together with the medical records upon which that statement or diagnosis is based or (b) a Claimant can provide the medical records that, themselves, will enable the Claims Office to place the Claimant on the Disease Payment Option 1 Schedule.

A Claimant should submit all records that contain information relevant to the criteria for Disease Payment Option 1, including (1) records relating to the relevant signs, symptoms, findings and test results set forth in Disease Payment Option 1 and (2) records showing the severity of a Claimant's disease or, if applicable, a determination of disability level by either a Qualified Medical Doctor or the Claimant's treating physician. In general, whatever the physician relied upon in arriving at the diagnosis and findings in the statement or diagnosis should be provided. Typically, this might include a patient questionnaire, physical findings obtained from an assistant's notes in the office chart, and certain lab or other test reports. If the doctor needed to review earlier medical records obtained from other physicians to make a definitive statement about the Claimant's condition or disability, then those records must also, if available, be submitted. If, however, based on an examination of the Claimant, the physician has first-hand knowledge of everything that is the basis for his or her opinion, and the statement or diagnosis sets out that knowledge in sufficient detail, it is possible that no additional records will be required.

As used herein, the term "Qualified Medical Doctor" or "QMD" means a physician who is Board-certified (not Board-eligible) in internal medicine, rheumatology (a sub-specialty of internal medicine), neurology, neurological surgery, or immunology who prepares the statement or diagnosis that the Claimant must file in support of a Disease Payment Option 1 Claim. Only a Board-certified physician can submit the statement or diagnosis of one of the compensable diseases included in Disease Payment Option 1. The physician writing a statement or diagnosis of one of the compensable diseases in Disease Payment Option 1 must be Board-certified in an appropriate specialty. The type of specialty depends on the complaints and symptoms with which a Claimant presents. "Board-certified" means certification in a particular medical specialty by the American Board of Medical Specialists. A Doctor of Osteopathy can be a Qualified Medical Doctor if he or she is Board-certified by the same Board that certifies Medical Doctors. A Doctor of Osteopathy may also submit diagnoses or disease compensation claims so long as his or her certification is within an appropriate specialty.

The Claims Office is authorized to determine whether physicians in other countries have degrees or certifications that are the equivalent of those accorded in the United States and should therefore be treated as Qualified Medical Doctors. The Claims Office shall determine which certification systems of foreign countries are the equivalent of U.S. Board certification using the procedures applied by the MDL 926 Claims Administrator in the Foreign Settlement Program. The Plan Proponents or the Claimants' Advisory Committee and Debtor's Representatives shall specify the categories, degrees or certification of doctors that will qualify as Qualified Medical Doctors in Class 6.2 countries.

As used herein, the term "treating physician" is one who has seen, examined, and treated the Claimant on several occasions, and not a doctor whom the Claimant has seen only for purposes of getting an evaluation to make a claim under this Disease Payment Option. Treating physician includes a Qualified Medical Doctor if such Qualified Medical Doctor states that he or she has the information necessary to form a professional opinion about the Claimant's disability and sets forth in the statement or diagnosis (or in a supplemental statement) the information upon which that opinion is based and the source of that information.

As used herein, the term "documented" means that it is based on some reliable information other than simply the Claimant's complaint or oral history. For some symptoms, "documented" means that the physician has verified the symptom on physical examination or through a lab test. For others, primarily those that are entirely subjective, it can mean that the physician has performed a physical examination and questioned the Claimant sufficiently to be able to form a professional opinion, utilizing all that doctor's knowledge and training, that the complaint is a valid one. (In this situation, it is important that the physician relying on these complaints does not qualify the diagnosis by stating that these "findings" are based solely on the patient's history given at the time of the single visit to the Board-certified specialist. The physician needs to feel confident in concluding that the problems do indeed exist.) "Documented" can also mean that written notations of that symptom are found several places in the Claimant's medical records. Thus, to show that a symptom is "documented," a Claimant can submit (1) proof of verification of the symptom through physical examination; (2) a statement from the Claimant's QMD revealing that (s)he questioned the Claimant sufficiently about the symptom and concluded that the complaint is valid; or (3) medical records reflecting that the Claimant had complained about this symptom on other occasions.

To the extent the severity of a Claimant's disease is based on a disability rating, as defined herein, the Claimant must submit all of the records that the physician relied upon in making his or her disability determination. This would include, as an example, any disability questionnaire that the Claimant completed in order to assist in the physician's determination. A non-Board-certified treating physician can provide a disability determination.

In preparing submissions for Disease and Disability Option 1 and in curing any deficiencies that may be noted when the submission is processed, Claimants and their physicians (and their counsel if applicable) should be aware that the disability must be related to the compensable condition. That is, the pain must be due to the Claimant's Atypical Connective Tissue Disease or Atypical Neurological Disease. Thus, a threshold requirement in evaluating a disability submission is whether the Claimant's qualifying symptoms are ones such as alopecia, chronic fatigue, or loss of breast function that normally have no pain component. A disability determination cannot be approved unless there is evidence that the Claimant is experiencing pain from at least one (1) of her qualifying symptoms or unless the Claimant, in response to a deficiency determination, supplies evidence that she has an additional qualifying symptom

that does cause pain. In addition, Claimants and their physicians (and their counsel if applicable) should be aware that a "C" level disability requires that the pain be "regular or recurring." Thus, if a Claimant's pain is described in her records as being only "mild" or "slight," the disability determination will not be approved.

With respect to a claim for a "B" level disability, the claim must be based on severe pain or an inability to do certain activities. In order to qualify, there must be pain-producing symptoms that result in severe pain on a regular or recurring basis. Generalized statements about "severe pain" may not be enough. The Claims Office must be able to verify that the Atypical Connective Tissue Disease or Atypical Neurological Disease symptoms themselves are the cause of the severe pain. If the "B" level disability claim is based on limitations on a Claimant's activities, the claim submission must provide information concerning the activities that are limited. A conclusory statement, with no information about the Claimant and her limitations, will result in a deficiency being assigned. The disability assessment must demonstrate a connection between the specific activities that the Claimant can no longer perform. The disability must be due to the compensable condition. The Claims Office must have enough information about what the limitations are and the cause of those limitations to be able to verify that the Claimant's condition indeed meets the requirements for a "B" disability level.

In preparing a claim for an "A" level disability, Claimants and their physicians (and their counsel, if applicable) should be aware that the definition of this assigned disability level is a difficult one to meet. A Claimant must be unable to do any of her normal activities or only be able to do a very few of them. In preparing a submission, it should be reviewed to determine whether there is enough description of the Claimant's daily life and limitations to allow a reader to know that she does indeed meet this strict definition of total disability. In addition, it must be clear that the Claimant's total disability is due to the symptoms of the applicable disease or condition.

Generalized statements by the QMD that track the disease and disability language cannot replace the responsibility of the Claims Office to review, on a detailed level, all of the claim documentation provided.

If the Breast Implant Claimant's Qualified Medical Doctor determines that her death or total disability is clearly and specifically caused by a disease or occurrence other than the compensable disease, she will not be eligible for compensation in Severity/Disability Category A.

DISEASE PAYMENT OPTION 1: DEFINITION OF COVERED CONDITIONS

SYSTEMIC SCLEROSIS/SCLERODERMA (SS)

1. A diagnosis of systemic sclerosis shall be made in accordance with the criteria established in Kelley, et al., Textbook of Rheumatology (4th ed.) at 1113, et seq.

2. Application of these diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of classical systemic sclerosis but who nonetheless have a systemic sclerosis-like (scleroderma-like) disease, except that an individual will not be compensated in this category if her symptomology more closely resembles MCTD, ACTD, or any other disease or condition defined below. A "systemic sclerosis-like" or "scleroderma-like" disease is defined as an autoimmune/rheumatic disease that fulfills most of the accepted standards for the diagnosis of systemic sclerosis but is in some manner atypical of systemic sclerosis or scleroderma.

3. Severity/Disability Compensation Categories

A. Death or total disability resulting from SS or an SS-like condition. An individual will be considered totally disabled if the individual satisfies the functional capacity test set forth in Severity/Disability Category A for ACTD/ARS/NAC or if the individual suffers from systemic sclerosis with associated severe renal involvement manifested by a decrease in glomerular filtration rates.

B. Cardio-pulmonary involvement or diffuse (Type III) scleroderma as defined by Barnett, A Survival Study of Patients with Scleroderma Diagnosed Over 30 Years (1953 - 1983): The Value of a Simple Cutaneous Classification in the Early Stages of the Disease, 15 The Journal of Rheumatology 276 (1988) and Masi, Classification of Systemic Sclerosis (Scleroderma): Relationship of Cutaneous Subgroups in Early Disease to Outcome and Serologic Reactivity, 15 The Journal of Rheumatology, 894 (1988).

C. Other including CREST, limited, or intermediate scleroderma, except that any Breast Implant Claimant who manifests either severe renal involvement, as defined above, or cardio-pulmonary involvement, will be compensated at either category A or B as appropriate.

D. Other not covered above, including localized scleroderma.

SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

1. A diagnosis of systemic lupus erythematosus (SLE) shall be made in accordance with 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus, 25 Arthritis and Rheumatism No. 11 (November 1982) adopted by the American College of Rheumatology. See Kelley, 4th ed. at 1037, Table 61-11: A diagnosis of lupus is made if four (4) of the eleven (11) manifestations listed in the table were present, either serially or simultaneously, during any interval of observations.

CRITERION	DEFINITION
Malar rash	Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds
Discoid rash	Erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions
Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by patient history or physician observation
Oral ulcers	Oral or nasopharyngeal ulceration, usually painless, observed by a physician
Arthritis	Nonerosive arthritis involving two or more peripheral joints, characterized by tenderness, swelling or effusion
Serositis	(a) Pleuritis – convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion or (b) Pericarditis – documented by ECG or rub or evidence of pericardial effusion
Renal disorder	(a) Persistent proteinuria greater than 0.5 g/day or greater than three (3) + if quantitation not performed or (b) Cellular casts - may be red cell, hemoglobin, granular, tubular, or mixed
Neurologic disorder	(a) Seizures - in the absence of offending drugs or known metabolic derangements; e.g., uremia, ketoacidosis, or electrolyte imbalance or (b) Psychosis - in the absence of offending drugs or known metabolic derangements; e.g. uremia, ketoacidosis, or electrolyte imbalance
Hematologic disorder	(a) Hemolytic anemia - with reticulocytosis or (b) Leukopenia - less than 4000/mm total on two (2) or more occasions or (c) Lymphopenia - less than 1500/mm on two (2) or more occasions or (d) Thrombocytopenia - less than 100,000/mm in the absence of offending drugs
Immunologic disorder	(a) Positive LE cell preparation or (b) Anti-DNA - antibody to native DNA in abnormal titer or (c) Anti-Sm - presence of antibody to Sm nuclear antigen or (d) False positive serologic test for syphilis known to be positive for at least six (6) months and confirmed by Treponema pallidum immobilization or fluorescent treponemal antibody absorption test
Antinuclear antibody	An abnormal titer of antinuclear antibody by immunofluorescence or an equivalent assay at any point in time and in the absence of drugs known to be associated with drug-induced lupus syndrome

2. The application of the ACR diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of SLE but who nonetheless have a systemic lupus erythematosus-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles mixed connective tissue disease (MCTD), ACTD, or any other disease or condition defined below.

3. Severity/Disability Compensation Categories:

A. Death or total disability resulting from SLE or an SLE-like condition. An individual will be considered totally disabled based on either the functional capacity test set forth in Severity/Disability Category A for ACTD/ARS/NAC or severe renal involvement.

B. SLE with major organ involvement defined as SLE with one (1) or more of the following: glomerulonephritis, central nervous system involvement (i.e. seizures or Lupus Psychosis), myocarditis, pneumonitis, thrombocytopenic purpura, hemolytic anemia (marked), severe granulocytopenia, mesenteric vasculitis. See Immunological Diseases, Max Samter, Ed. Table 56-6, at 1352.

C. Non-major organ SLE requiring regular medical attention, including doctor visits and regular prescription medications. An individual is not excluded from this category for whom prescription medications are recommended but who, because of the side effects of those medications, chooses not to take them.

D. Non-major organ SLE requiring little or no treatment. An individual will fall into this category if she is able to control her symptoms through the following kinds of conservative measures: over-the-counter medications, avoiding sun exposure, use of lotions for skin rashes, and increased rest periods.

ATYPICAL NEUROLOGICAL DISEASE SYNDROME (ANDS)

1. A diagnosis of Atypical Neurological Disease Syndrome (ANDS) shall be based upon the clinical findings and laboratory tests set forth below. The clinical and laboratory presentation of these neurological syndromes will have an atypical presentation from the natural disease and will also have additional neuromuscular, rheumatological or nonspecific autoimmune signs and symptoms.

2. Eligibility for Atypical Neurological Disease Syndrome requires both:

- satisfying the requirements for one (1) of the four (4) neurological diseases set forth in paragraph 5 below, *and*
- any three (3) additional (nonduplicative) neuromuscular, rheumatic, or nonspecific symptoms or findings set forth in the definition for Atypical Connective Tissue Disease (ACTD).

3. An individual will fit into this category if her primary symptoms are characteristic of a neurological disease as diagnosed by a Board-certified neurologist or by a physician Board-certified in internal medicine.

4. If the individual's Qualified Medical Doctor determines that a symptom is clearly and specifically caused by a source other than breast implants, that symptom will not be utilized in the diagnosis of Atypical Neurological Disease Syndrome unless the Claims Office determines that other submissions indicate that the symptom should be utilized. A symptom that may be caused only in part by a source other than breast implants is not excluded from such utilization.

5. Neurological disease types:

Polyneuropathies. This disease category requires either (1) a diagnosis of a polyneuropathy that is confirmed by one or more of the following or (2) submission of sufficient evidence of, and the required findings confirming, such condition:

- ♦ Objectively-demonstrated loss of sensation to pinprick, vibration, touch, or position
- ♦ Proximal or distal muscle weakness
- ♦ Tingling and/or burning pain in the extremities
- ♦ Signs of dysesthesia
- ♦ Loss of tendon reflex

Plus one (1) or more of the following laboratory findings:

- ♦ Abnormal levels of anti-mag or anti-sulfatide or anti-GM1 antibodies
- ♦ Abnormal sural nerve biopsy
- ♦ Abnormal electrodiagnostic testing (EMG or nerve conduction studies, etc.)

Multiple Sclerosis-like Syndrome. This disease category requires definite evidence of central nervous system disease, with history and physical findings compatible with Multiple Sclerosis or Multiple Sclerosis-like syndrome, involving one (1) or more of the following signs and symptoms:

- ♦ Weakness in the pyramidal distribution
- ♦ Evidence of optic neuritis documented by ophthalmologist
- ♦ Increased Deep Tendon reflexes
- ♦ Absent superficial abdominal reflexes
- ♦ Ataxia or dysdiadochokinesia as the sign of cerebellar involvement

- Neurologically induced tremors
- Internuclear ophthalmoplegia and/or bladder or speech involvement secondary to central nervous system disease

Plus one (1) or more of the following:

- Abnormal Brain MRI with foci of increased signal abnormality suggestive of demyelinating lesions
- Delayed visual evoked responses or abnormal evoked potentials
- Abnormal CSF with oligoclonal bands

ALS-like Syndrome. This disease category requires documented evidence of progressive upper and widespread lower motor neuron disease and/or bulbar involvement, plus one (1) or more of the following:

- Neurological autoantibodies such as anti-mag, anti-sulfatide, anti-GM1
- Abnormal sural nerve biopsy
- Chronic inflammation on muscle or nerve biopsies
- Abnormal EMG
- Documentation on neurological exam of both upper and lower motor neuron disease and/or bulbar involvement

Disease of Neuromuscular Junction. This disease category requires either (1) a diagnosis of Myasthenia Gravis or Myasthenia Gravis-like syndrome or disorders of the NMJ, made by a Board-certified neurologist and confirmed by abnormal EMG showing typical findings of decrement on repetitive stimulation testing and/or elevated acetylcholine receptor antibodies or (2) submission of sufficient evidence of, and the required findings confirming, such condition.

6. Severity/Disability Compensation Categories. The compensation level for ANDS will be based on the degree to which the individual is "disabled" by the condition, as the individual's treating physician determines in accordance with the following guidelines. The determination of disability under these guidelines will be based on the cumulative effect of the symptoms on the individual's ability to perform her vocational, avocational, or usual self-care, activities. In evaluating the effect of the individual's symptoms, the treating physicians will take into account the level of pain and fatigue resulting from the symptoms. The disability percentages appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the physician in the exercise of his or her professional judgment.

A. Death or total disability due to the compensable condition. An individual shall be considered totally disabled if she demonstrates a functional capacity adequate to consistently perform none or only few of the usual duties or activities of vocation or self-care.

B. A Breast Implant Claimant will be eligible for category B compensation if she is 35% disabled due to the compensable condition. 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 self-care, or if she can only perform them with regular or recurring severe pain.

C. A Breast Implant Claimant will be eligible for category C compensation if she is 20% disabled due to the compensable condition. An individual shall be considered 20% disabled if she can perform some of her usual activities of vocation, avocation, and self-care with regular or recurring moderate pain.

MIXED CONNECTIVE TISSUE DISEASE (MCTD)/OVERLAP SYNDROME

1. A diagnosis of mixed connective tissue disease (MCTD) shall be based on the presence of clinical symptoms characteristic of two (2) or more rheumatic diseases (systemic sclerosis, SLE, myositis, and Rheumatoid Arthritis), accompanied by positive RNP Antibodies. See, e.g., Kelley, et al., Table 63-1, at 1061.

2. Overlap Syndrome is defined as any one (1) of the following three (3): (a) Diffuse cutaneous scleroderma, (b) limited cutaneous scleroderma, or (c) Sine scleroderma, occurring concomitantly with diagnosis of systemic lupus erythematosus, inflammatory muscle disease, or rheumatoid arthritis. See Kelley, et al., Table 66-2, at 1114.

3. The application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of MCTD but who nonetheless have an Overlap Syndrome, except that an individual will not be compensated in this category if her symptomology more closely resembles an atypical connective tissue disease condition/atypical rheumatic syndrome/non-specific autoimmune condition.

4. Severity/Disability Compensation Categories

A. Death or total disability resulting from MCTD or Overlap Syndrome. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A of Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.

B. MCTD or Overlap Syndrome, plus major organ involvement or major disease activity including central nervous system, cardio-pulmonary, vasculitic, or renal involvement or hemolytic anemia (marked) or thrombocytopenic purpura or severe granulocytopenia.

C. Other.

POLYMYOSITIS/DERMATOMYOSITIS

1. A diagnosis of polymyositis or dermatomyositis shall be made in accordance with diagnostic criteria proposed by Bohan and Peter, i.e., (a) symmetrical proximal muscle weakness; (b) EMG changes characteristic of myositis including (1) short duration, small, low amplitude polyphasic potential, (2) fibrillation potentials, (3) bizarre high-frequency repetitive discharges; (c) elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT, and LDH); (d) muscle biopsy showing evidence of necrosis of type I and II muscle fibers, areas of degeneration and regeneration of fibers, phagocytosis, and an interstitial or perivascular inflammatory response; (e) dermatologic features including a lilac (heliotrope), erythematous, scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli, and Gottron's papules. A diagnosis of dermatomyositis requires presence of three (3) of the criteria plus the rash (fifth criterion). A diagnosis of polymyositis requires the presence of four (4) criteria without the rash. See Kelley, et al., at 1163.

2. The application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of polymyositis or dermatomyositis but who nonetheless have a polymyositis or dermatomyositis-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles an Atypical Connective Tissue Disease.

3. Severity/Disability Compensation Categories:

A. Death or total disability resulting from polymyositis or dermatomyositis. An individual will be considered totally disabled based on the functional capacity test set forth for Severity/Disability Category A for Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.

B. Polymyositis or dermatomyositis with associated malignancy and/or respiratory muscle involvement.

C. Other, including polymyositis or dermatomyositis with muscle strength of Grade III or less.

PRIMARY SJOGREN'S SYNDROME

1. A clinical diagnosis of Primary Sjogren's Syndrome shall be made in accordance with diagnostic criteria proposed by Fox et al. See Kelley, et al., Table 55-1, at 932, or Fox, RI, et al., "Primary Sjogren's Syndrome: Clinical and Immunopathologic Features," Seminars Arthritis Rheum., 1984; 4:77-105.

2. Application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of Primary Sjogren's Syndrome but who nonetheless have a Primary Sjogren's-like disease.

3. Severity/Disability Compensation Categories

A. Death or total disability due to the compensable condition. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A for Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.

B. Primary Sjogren's with associated central nervous system or severe cardio-pulmonary involvement or primary Sjogren's with pseudolymphoma or associated lymphoma.

C. Other.

ATYPICAL CONNECTIVE TISSUE DISEASE (ACTD)
ATYPICAL RHEUMATIC SYNDROME (ARS)
NON-SPECIFIC AUTOIMMUNE CONDITION (NAC)

1. This category will provide compensation for Breast Implant Claimants experiencing symptoms that are commonly found in autoimmune or rheumatic diseases but which are not otherwise classified in any of the other compensable disease categories. This category does not include individuals who have been diagnosed with classical rheumatoid arthritis in accordance with ACR criteria, but will include individuals diagnosed with undifferentiated connective tissue disease (UCTD). However, such inclusion is not intended to exclude from this category persons who do not meet the definition of UCTD, it being intended that individuals not meeting the classic definitions of UCTD will be compensated pursuant to the provisions contained herein relative to ACTD, ARS, and NAC.

2. As with other individuals who fit within this disease compensation program, the fact that a breast implant recipient has been in the past mis-diagnosed with classic rheumatoid arthritis or the fact that the symptoms of classic rheumatoid arthritis may coexist with other symptoms will not exclude the individual from compensation herein. Persons who meet the criteria below and may have a diagnosis of atypical rheumatoid arthritis will not be excluded from compensation under this category.

3. Eligibility criteria and compensation levels for eligible Breast Implant Claimants are set forth below in the Compensation Categories, which classify individuals in accordance with the following groups of symptoms. If the Breast Implant Claimant's Qualified Medical Doctor determines that a symptom is clearly and specifically caused by a source other than breast implants, that symptom will not be utilized in the diagnosis of Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome unless the Claims Office determines that other submissions indicate that the symptom should be utilized. A symptom that may be caused only in part by a source other than breast implants is not excluded from such utilization.

4. A diagnosis of ACTD, ARS, or NAC must satisfy one (1) of the following sets of criteria:

- any two (2) of the three (3) signs and symptoms listed in 5(a) (Group I)
- any one (1) of the three (3) signs and symptoms listed in 5(a) (Group I), plus any one (1) of the ten (10) signs and symptoms listed in 5(b) (Group II)

- any three (3) of the ten (10) signs and symptoms listed in 5(b) (Group II)
- any two (2) of the ten (10) signs and symptoms listed in 5(b) (Group II), plus any one (1) additional (nonduplicative) sign or symptom from the eighteen (18) listed in 5(c) (Group III)
- five (5) nonduplicative signs or symptoms listed in 5(a) (Group I), 5(b) (Group II), or 5(c) (Group III)

5. Symptom Groupings:

(a) Group I Signs and Symptoms:

- Raynaud's phenomenon evidenced by the patient giving a history of two (2) color changes, or visual evidence of vasospasm, or evidence of digital ulceration
- Polyarthritis defined as synovial swelling and tenderness in three (3) or more joints lasting greater than six (6) weeks and observed by a physician
- Keratoconjunctivitis Sicca: subjective complaints of dry eyes and/or dry mouth, accompanied by any one (1) of the following:
  - lacrimal or salivary enlargement
  - parotid enlargement
  - abnormal Schirmer's test
  - abnormal Rose-Bengal staining
  - filamentous keratitis
  - abnormal parotid scan or ultrasound
  - abnormal CT or MRI of parotid
  - abnormal labial salivary biopsy

(b) Group II Signs and Symptoms:

- Myalgias determined by tenderness on examination
- Immune mediated skin changes or rash as follows:
  - changes in texture or rashes that may or may not be characteristic of SLE, Systemic Sclerosis (scleroderma), or dermatomyositis
  - diffuse petechiae, telangiectasias, or livedo reticularis

- ♦ Pulmonary symptoms or abnormalities, which may or may not be characteristic of SLE, Systemic Sclerosis (scleroderma), or Sjogren's Syndrome, as follows:

  - pleural and/or interstitial lung disease
  - restrictive lung disease
  - obstructive lung disease as evidenced by characteristic clinical findings and either:

    characteristic chest X-ray changes *or*
    characteristic pulmonary function test abnormalities in a non-smoker (e.g. decreased DLCO or abnormal arterial blood gases)

- ♦ Pericarditis defined by consistent clinical findings and either EKG or echocardiogram

- ♦ Neuropsychiatric symptoms: cognitive dysfunction (memory loss and/or difficulty concentrating) which may be characteristic of SLE or MCTD as determined by a SPECT scan or PET scan or MRI or EEG or neuropsychological testing

- ♦ Peripheral neuropathy diagnosed by physical examination showing one (1) or more of the following:

  - loss of sensation to pinprick, vibration, touch, or position
  - tingling, paresthesia or burning pain in the extremities
  - loss of tendon reflex
  - proximal or distal muscle weakness (loss of muscle strength in extremities or weakness of ankles, hands, or foot drop)
  - Signs of dysesthesia
  - entrapment neuropathies

- ♦ Myositis or myopathy:

  - diagnosed by weakness on physical examination or by muscle strength testing
  - abnormal CPK or aldolase

- abnormal cybex testing
- abnormal EMG
- abnormal muscle biopsy

♦ Serologic abnormalities – any one (1) of the following:

- ANA > or equal to 1:40
- positive ANA profile such as Anti-DNA, SSA, SSB, RNP, SM, Scl-70, centromere, Jo-1, PM-Scl or dsDNA (preferable to use ELISA with standard cutoffs)
- other autoantibodies, including thyroid antibodies, anti-microsomal, or anti-cardiolipin, or RF (by nephelometry with 40 IU cutoff)
- elevation of immunoglobulin (IgG, IgA, IgM)
- serologic evidence of inflammation such as elevated ESR, CRP

♦ Lymphadenopathy (as defined by at least one (1) lymph node greater than or equal to 1x1 cm) documented by a physician

♦ Dysphagia with positive cine-esophagram, manometry or equivalent imaging

(c) Group III Signs and Symptoms:

♦ Documented arthralgia

♦ Documented Myalgias

♦ Chronic fatigue

♦ Lymphadenopathy

♦ Documented Neurological symptoms including cognitive dysfunction or paresthesia

♦ Photosensitivity

♦ Sicca symptoms

♦ Dysphagia

♦ Alopecia

- ♦ Sustained balance disturbances
- ♦ Documented sleep disturbances
- ♦ Easy bruisability or bleeding disorder
- ♦ Chronic cystitis or bladder irritability
- ♦ Colitis or bowel irritability
- ♦ Persistent low grade fever or night sweats
- ♦ Mucosal ulcers confirmed by physician
- ♦ Burning pain in the chest, breast, arms or axilla, or substantial loss of function in breast due to disfigurement or other complications from implants or explantation
- ♦ Pathological findings: granulomas or siliconomas or chronic inflammatory response, or breast infections

6. Severity/Disability Compensation Categories

The compensation level for ACTD/ARS/NAC will be based on the degree to which the individual is "disabled" by the condition, as the individual's treating physician determines in accordance with the following guidelines. The determination of disability under these guidelines will be based on the cumulative effect of the symptoms on the individual's ability to perform her vocational[3], avocational[4], or usual self-care[5] activities. In evaluating the effect of the Breast Implant Claimant's symptoms, the treating physicians will take into account the level of pain and fatigue resulting from the symptoms. The disability percentages appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the physician in the exercise of his or her professional judgment.

A. 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 few of the usual duties or activities of vocation or self-care.

B. A Breast Implant Claimant will be eligible for category B compensation if she is 35% disabled due to the compensable condition. 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 self-care, or she can perform them only with regular or recurring severe pain.

C. A Breast Implant Claimant will be eligible for category C compensation if she is 20% disabled due to the compensable condition. An individual shall be considered 20% disabled if she can perform some of her usual activities of vocation, avocation, and self-care only with regular or recurring moderate pain.

[3] Vocational means activities associated with work, school, and homemaking.
[4] Avocational means activities associated with recreation and leisure.
[5] Usual self-care means activities associated with dressing, feeding, bathing, grooming, and toileting.

PART B. DISEASE AND DISABILITY/SEVERITY DEFINITIONS: DISEASE PAYMENT OPTION 2

GENERAL GUIDELINES

A. A claimant must file with the Claims Office all medical records establishing the required findings or laboratory abnormalities. Qualifying findings must have occurred within a single 24-month period within the five (5) years immediately preceding the submission of the claim except that this period is tolled during the pendency of the bankruptcy (May 15, 1995 until the Effective Date). (Findings supplemented in response to a deficiency letter sent by the Claims Office do not have to fall within the 24-month period outlined above.)

B. If exclusions are noted for a required finding, the physician making the finding or ordering the test must affirmatively state that those listed exclusions are not present. The physician recording a GCTS finding or making a disease diagnosis must also affirmatively state that the qualifying symptoms did not exist before the date of first implantation. (This statement can be based upon patient history so long as consistent with medical records in the physician's possession.) Failure to make these affirmative statements will result in a deficiency letter. All underlying office charts, radiology/pathology reports, and test results must be supplied to the Claims Office.

C. QMD statements may be acceptable proof under Disease Payment Option 2 if the physician is a Board-certified rheumatologist — for Lupus, Scleroderma, or Polymyositis/Dermatomyositis Claims — or is Board-certified in the appropriate specialty to make the required GCTS findings, if the statement covered all of the detailed findings that are required in Disease Payment Option 2, if the QMD personally examined the Claimant, and if the doctor included all of the additional statements required concerning listed exclusions and pre-existing symptoms. In most cases, additional physician statements will have to be submitted for claims under Disease Payment Option 2.

D. Claimants who seek benefits under Disease Payment Option 2 must file all medical records establishing the required findings or laboratory abnormalities. Claimants must also supply all office charts, radiology/pathology reports, and test results in the possession of the physician(s) who make the required findings or statements, or who order the required tests.

DISEASE PAYMENT OPTION 2: DEFINITION OF COVERED CONDITIONS

SCLERODERMA (SS)

A claim for scleroderma must include a diagnosis of systemic sclerosis/scleroderma made by a Board-certified rheumatologist based upon personal examination of the patient. [Exclusion: localized scleroderma.] Supporting medical documentation must affirmatively reveal that the major or at least two (2) of the minor criteria listed below are present:

A. *Major Criterion:* Proximal scleroderma — symmetric thickening, tightening, and induration of the skin of the fingers and the skin proximal to the metacarpophalangeal or metatarsophalangeal joints. The changes may affect the entire extremity, face, neck, and trunk (thorax and abdomen). Description of this criterion is adequate if the Board-certified rheumatologist records that physical examination of the patient revealed scleroderma skin thickening, and adequately describes the parts of the body where that thickened skin was found.

B. *Minor Criteria:*

1. Sclerodactyly: Above-indicated skin changes limited to the fingers.

2. Digital pitting scars or loss of substance from the finger pad: Depressed areas at tips of fingers or loss of digital pad tissue as a result of ischemia.

3. Bibasilar pulmonary fibrosis: Bilateral reticular pattern of linear or lineonodular densities most pronounced in basilar portions of the lungs on standard chest roentgenogram; may assume appearance of diffuse mottling or “honeycomb lung.” These changes should not be attributable to primary lung disease.

Compensation Levels:

A. Death resulting from SS, or severe chronic renal involvement manifested by a glomerular filtration rate of less than 50% of the age- and gender-adjusted norm, as measured by an adequate 24-hour urine specimen collection.

B. Clinically significant cardio-pulmonary manifestations of scleroderma or proximal scleroderma on the trunk (thorax and abdomen).

C. A diagnosis of scleroderma in accordance with the above criteria that does not involve the findings in A or B above.

LUPUS (SLE)

A claim for SLE must include a diagnosis of SLE (lupus) made by a Board-certified rheumatologist based upon personal examination of the patient. [Exclusion: mild lupus (SLE not requiring regular medical attention including doctor visits and regular prescription medications).] Supporting medical documentation must affirmatively reveal that at least four (4) of the following eleven (11) criteria are present:

	Criterion	*Definition*
1.	Malar rash	Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds
2.	Discoid rash	Erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions
3.	Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by patient history or physician observation
4.	Oral ulcers	Oral or nasopharyngeal ulceration, usually painless, observed by a physician
5.	Arthritis	Nonerosive arthritis involving two or more peripheral joints, characterized by tenderness, swelling, or effusion [Exclusion: erosive arthritis]
6.	Serositis	(a) Pleuritis – convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion, or (b) Pericarditis — documented by ECG or rub or evidence of pericardial effusion
7.	Renal disorder	(a) Persistent proteinuria greater than 0.5 grams per day or greater than three (3)+ if quantitation not performed, or (b) Cellular casts – may be red cell, hemoglobin, granular, tubular, or mixed
8.	Neurologic disorder	Seizures – in the absence of offending drugs or known metabolic derangements, e.g. uremia, ketoacidosis, or electrolyte imbalance
9.	Hematologic disorder	a) Hemolytic anemia – with reticulocytosis, or b) Leukopenia — less than 4,000/mm total on two (2) or more occasions, or c) Lymphopenia — less than 1,500/mm on two (2) or more occasions, or d) Thrombocytopenia — less than 100,000/mm in the absence of offending drugs

10.	Immunologic disorder	a) Positive LE cell preparation, or b) Anti- DNA: antibody to native DNA in abnormal titer, or c) Anti-Sm: presence of antibody to Sm nuclear antigen, or d) False positive serologic test for syphilis known to be positive for at least six (6) months and confirmed by Treponema pallidum immobilization or fluorescent treponemal antibody absorption test
11.	Antinuclear antibody	An abnormal titer or antinuclear antibody by immuno-fluorescence or an equivalent assay at any point in time and in the absence of drugs known to be associated with "drug-induced lupus" syndrome.

Compensation Levels:

A. Death resulting from SLE, or severe chronic renal involvement manifested by a glomerular filtration rate of less than 50% of the age- and gender-adjusted norm, as measured by an adequate 24-hour urine specimen collection.

B. SLE with involvement of one (1) or more of the following: glomerulonephritis, seizures in the absence of offending drugs or known metabolic derangements, Lupus Psychosis, myocarditis, pneumonitis, thrombocytopenic purpura, hemolytic anemia (with hemoglobin of 10 grams or less), severe granulocytopenia (with a total white cell count less than 2000), or mesenteric vasculitis.

C. A diagnosis of lupus in accordance with the above criteria that does not involve the findings in A or B above. (Default compensation level.)

POLYMYOSITIS (PM)/DERMATOMYOSITIS (DM)

A claim for polymyositis or dermatomyositis must include a diagnosis of the disease made by a Board-certified rheumatologist based upon personal examination of the patient. Supporting medical documentation must affirmatively reveal that the following criteria are present:

- for polymyositis, the first four (4) criteria without the rash;
- for dermatomyositis, three (3) of the first four (4) criteria, plus the rash (#5).

Criteria:

1. symmetrical proximal muscle weakness;
2. EMG changes characteristic of myositis including (a) short duration, small, low-amplitude polyphasic potential, (b) fibrillation potentials, (c) bizarre high-frequency repetitive discharges;
3. elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT, and LDH);
4. muscle biopsy showing evidence of necrosis of type I and II muscle fibers areas of degeneration and regeneration of fibers, phagocytosis, and an interstitial or perivascular inflammatory response;

5. dermatologic features including a lilac (heliotrope), erythematous, scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli, and Gottron's papules.

Compensation Level:

All confirmed PM/DM diagnoses will be compensated at the GCTS/PM/DM – A level.

GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS)

A claim for GCTS does not have to include a diagnosis for "General Connective Tissue Symptoms," but the medical documentation must establish that the combination of findings listed below are present. [Exclusion: classical rheumatoid arthritis diagnosed in accordance with the revised 1958 ACR classification criteria.]

For compensation at Level A:
(1) any two (2) findings from Group I; or
(2) any three (3) non-duplicative findings from Group I or Group II.

For compensation at Level B:
(1) one (1) finding from Group I plus any four (4) non-duplicative findings from Group II or Group III; or
(2) two (2) findings from Group II plus one (1) non-duplicative finding from Group III.

The following duplications exist on the list of findings:
- rashes (#3 and #8)
- sicca (#2 and #12)
- serological abnormalities (#4 and #9)

In addition to the medical verification of the required findings, a claim for GCTS must include the affirmative physician statements outlined in General Guidelines above.

GROUP I FINDINGS

1. Polyarthritis, defined as synovial swelling and tenderness in three (3) or more joints in at least two (2) different joint groups observed on more than one (1) physical examination by a Board-certified physician and persisting for more than six (6) weeks. [Exclusion: osteoarthritis.]

2. Keratoconjunctivitis Sicca, defined as subjective complaints of dry eyes and/or dry mouth, accompanied (a) in the case of dry eyes, by either (i) a Schirmer's test less than 8 mm wetting per five minutes or (ii) a positive Rose-Bengal or fluorescein staining of cornea and conjunctiva; or (b) in the case of dry mouth, by an abnormal biopsy of the minor salivary gland (focus score of greater than or equal to two (2) based upon average of four (4) evaluable lobules). [Exclusions: drugs known to cause dry eyes and/or dry mouth, and dry eyes caused by contact lenses.]

3. Any of the following immune-mediated skin changes or rashes, observed by a Board-certified rheumatologist or Board-certified dermatologist: (a) biopsy-proven discoid lupus; (b) biopsy-proven subacute cutaneous lupus; (c) malar rash – fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds [Exclusion: rosacea or redness caused by sunburn]; or (d) biopsy-proven vasculitic skin rash.

GROUP II FINDINGS

4. Positive ANA greater than or equal to 1:40 (using Hep2), on two (2) separate occasions separated by at least two (2) months and accompanied by at least one (1) test showing decreased complement levels of C3 and C4; or a positive ANA greater than or equal to 1:80 (using Hep2) on two (2) separate occasions separated by at least two (2) months. All such findings must be outside of the performing laboratory's reference ranges.

5. Abnormal cardiopulmonary symptoms, defined as (a) pericarditis documented by pericardial friction rub and characteristic echocardiogram findings (as reported by a Board-certified radiologist or cardiologist); (b) pleuritic chest pain documented by pleural friction rub on exam and chest X-ray diagnostic of pleural effusion (as reported by a Board-certified radiologist); or (c) interstitial lung disease in a non-smoker diagnosed by a Board-certified internist or pulmonologist, confirmed by (i) chest X-ray or CT evidence (as reported by a Board-certified radiologist) and (ii) pulmonary function testing abnormalities defined as decreased DLCO less than 80% of predicted.

6. Myositis or myopathy, defined as any two (2) of the following: (a) EMG changes characteristic of myositis: short duration, small, low amplitude polyphasic potential; fibrillation potentials; and bizarre high-frequency repetitive discharges; (b) abnormally elevated CPK or aldolase from the muscle (outside of the performing laboratory's reference ranges) on two (2) separate occasions at least six (6) weeks apart. (If the level of the initial test is three (3) times normal or greater, one (1) test would be sufficient.) [Exclusions: injections, trauma, hypothyroidism, prolonged exercise, or drugs known to cause abnormal CPK or aldolase]; or (c) muscle biopsy (at a site that has not undergone EMG testing) showing evidence of necrosis of type 1 and 2 muscle fibers, phagocytosis, and an interstitial or perivascular inflammatory response interpreted as characteristic of myositis or myopathy by a pathologist.

7. Peripheral neuropathy or polyneuropathy, diagnosed by a Board-certified neurologist, confirmed by (a) objective loss of sensation to pinprick, vibration, touch, or position; (b) symmetrical distal muscle weakness; (c) tingling and/or burning pain in the extremities; or (d) loss of tendon reflex, plus nerve conduction testing abnormality diagnostic of peripheral neuropathy or polyneuropathy recorded from a site that has not undergone neural or muscular biopsy. [Exclusions: thyroid disease, antineoplastic treatment, alcoholism or other drug dependencies, diabetes, or infectious disease within the last three (3) months preceding the diagnosis.]

GROUP III FINDINGS

8. Other immune-mediated skin changes or rashes, observed by a Board-certified rheumatologist or Board-certified dermatologist: (a) livedo reticularis; (b) lilac (heliotrope), erythematous scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli; (c) Gottron's sign, pink to violaceous scaling areas typically found over the knuckles, elbows, and knees; or (d) diffuse petechiae.

9. Any of the following serologic abnormalities: (a) ANA greater than or equal to 1:40 (using Hep2) on two (2) separate occasions separated by at least two (2) months; (b) one (1) or more positive ANA profile: Anti-DNA, SSA SSB, RNP, SM, Scl-70, centromere, Jo-1 PM-Scl, or double-stranded DNA (using ELISA with standard cutoffs); (c) anti-microsomal, anti-cardiolipin, or RF greater than or equal to 1:80.

10. Raynaud's phenomenon, evidenced by a physician-observed two (2) (cold-related) color change as a progression, or by physician observation of evidence of cold-related vasospasm, or by physician observation of digital ulceration resulting from Raynaud's phenomenon.

11. Myalgias, defined as tenderness to palpation, performed by a physician, in at least three (3) muscles, each persisting for at least six (6) months.

12. Dry mouth, subjective complaints of dry mouth accompanied by decreased parotid flow rate using Lashley cups with less than 0.5 ml per five minutes. [Exclusion: drugs known to cause dry mouth.]