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MDL-926 REVISED BREAST IMPLANT SETTLEMENT  
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QUESTIONS AND ANSWERS  
ABOUT LONG TERM BENEFIT CLAIMS FOR SCLERODERMA (SS)

The questions and answers in this pamphlet address many issues important to claimants making a long term benefit claim for Scleroderma (SS).

Section 1	General Questions
Section 2	Exclusions and Affirmative Statements
Section 3	Major Criterion
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Section 5	Compensation Levels

SECTION 1 GENERAL QUESTIONS

1. What is scleroderma?

Scleroderma is a chronic and progressive disease that causes inflammation and thickening of the skin and the formation of scar tissue in organs. The term "scleroderma," (also referred to as sclerosis) encompasses two groups: localized scleroderma or morphea, where the problems are confined to the skin, and systemic or diffuse sclerosis where internal organs (esophagus, kidneys, lungs, bowels) and blood vessels are involved as well as skin.

2. Are both kinds of scleroderma eligible for long term benefits?

No. Only systemic scleroderma (SS) is compensable under the long term benefit program.

3. Where can I find the exact criteria for scleroderma?

For purposes of the settlement, the criteria for scleroderma are found in Exhibit E1 – Revised Disease and Severity Definitions – to the Court's Order No. 27.

4. How can I get a copy of that document?

You can call the Claims Office at 1-800-600-0311 or visit our website at [www.claimsoffice-926.com/pdf/mdl926\\_exhibit\\_E1.pdf](http://www.claimsoffice-926.com/pdf/mdl926_exhibit_E1.pdf).

5. What is necessary to document a diagnosis of systemic scleroderma?

You must have a diagnosis of systemic scleroderma from a board-certified rheumatologist (BCR) based upon personal examination. The exact words that the

doctor uses may vary, but it must be clear from his statement and the records submitted that the doctor is making the diagnosis of systemic sclerosis or scleroderma.

**6. What should I submit to support my scleroderma claim?**

- All medical records (including lab reports) that document your qualifying symptoms and the diagnosis of systemic scleroderma; and
- A statement from the BCR that you do not have only localized scleroderma (morphea); and
- A statement from the BCR that you did not have any of the qualifying symptoms before you received your first breast implant. (This statement can be based on a patient's history as long as it is consistent with the medical records in your physician's possession); and
- All qualifying symptoms must have occurred within a 24 month period within the five years preceding the submission of your claim; and
- Supporting medical documentation must affirmatively reveal that the major (see Section 4) or at least two of the minor (see Section 5) criteria are present.

**7. Can my physician write a letter to summarize my symptoms?**

A letter may be written; however, it is the underlying records that are required to support your findings.

**8. My physician documented all the findings, the exclusion statement and the not pre-existing statement, but he did not sign the letter that stated my symptoms did not exist before my first implantation. Must I ask him to sign this statement?**

Yes. Your physician must sign all statements that are required to establish a disease claim, including both the exclusion statement and the not pre-existing statement.

**9. What is the five (5) year time frame?**

The five (5) year time frame refers to the five years preceding the submission of your claim.

**10. What is the twenty-four (24) month time frame?**

All qualifying symptoms must have occurred within a single twenty-four (24) month period.

**11. How do I get a phone call from a Claims Officer to discuss my claim?**

For general questions, you may call the Claims Office at any time. For specific questions regarding your claim, please send a completed and signed Request For Assistance Form to the Claims Office. A Claims Officer will review your file and call you to discuss your claim in detail.

**12. How do I get a re-review of my claim?**

Send a completed and signed Request for Re-review Form together with any additional information to be reviewed to the Claims Office.

**13. Where do I get these forms?**

All forms and information concerning the settlement can be obtained by calling 1-800-600-0311. In addition, many of the forms may be obtained from the Claims Office website at [www.claimsoffice-926.com](http://www.claimsoffice-926.com).

**14. How long do I have to send in additional information about my claim?**

For the claimants who receive a deficiency letter before December 15, 2009, the claimants have until December 15, 2010 (the stated end of the program) to complete their claim. Any such claim not completed and ready for payment based on materials postmarked by that date will be barred.

For those claimants who receive their first deficiency letter on or after December 15, 2009, the claimant will have one year from the date of the deficiency letter to complete their claim. Any such claim not complete and ready for payment based on materials postmarked by that date will be barred.

**15. Do I have to correct all the deficiencies in my SS letter?**

Not necessarily. It is only necessary to cure the deficiencies for those symptoms that are needed to meet either Compensation Level A, Compensation Level B or Compensation Level C.

**16. I have not been able to establish all the findings necessary for Level A, Level B or Level C compensation. Can I receive partial compensation for the symptoms I have established?**

No. You must meet all the criteria of a particular compensation level to receive any compensation for your SS symptoms.

**SECTION 2 EXCLUSIONS AND AFFIRMATIVE STATEMENTS**

**17. What are the exclusions for scleroderma?**

An exclusion is a condition that may exist which could disqualify a claimant from qualifying for compensation for scleroderma or a major or minor criterion thereof. The two exclusions that must be addressed are that your scleroderma is not "localized" and that your scleroderma symptoms did not exist before your first implantation.

**18. What is an exclusion statement and who can provide this statement?**

The exclusion statement is a required written statement by the BCR who makes the diagnosis of scleroderma and which specifically addresses the two exclusions. Please note, merely stating "the exclusion is not present" is not sufficient because both exclusions must be specifically mentioned.

**19. Where are the exclusions found?**

The general exclusion that your symptoms did not exist before your first implantation is contained in paragraph I(B) of Exhibit E1. The exclusion for scleroderma is set apart by brackets within the body of the SS definition as noted in paragraph II of Exhibit E1. As stated above, Exhibit E1 is available by calling the Claims Office or visiting the Claims Office website at [www.claimsoffice-926.com/pdf/mdl926\\_exhibit\\_E1.pdf](http://www.claimsoffice-926.com/pdf/mdl926_exhibit_E1.pdf).

**20. Is there a specific exclusion for scleroderma? If so, what is it?**

The specific exclusion for scleroderma is localized scleroderma which is scleroderma limited to the skin only and, therefore, is not systemic sclerosis.

**21. If my board-certified rheumatologist states that I have "localized" scleroderma, will I be ineligible for benefits for Scleroderma?**

It depends. If your scleroderma began as localized scleroderma but later progressed to systemic sclerosis, such that you now have either the major criterion or at least two of the minor criteria, your earlier diagnosis of localized scleroderma will not prevent you from receiving compensation for your advanced condition. If, however, your scleroderma continues to be localized, you will not be eligible for compensation for scleroderma.

**22. What is meant by the phrase "affirmatively state that the qualifying symptoms did not exist before the date of first implantation?"**

This affirmative statement declares that the qualifying scleroderma symptoms did not exist before your first breast implantation. This statement can be based on a patient's history as long as it is consistent with the medical records in your physician's possession. Please note that Exhibit E1 requires that the physician's statement be affirmative. Statements that are not written affirmatively may be unsatisfactory and generate a deficiency letter from the Claims Office.

**23. Who can make the affirmative statement?**

Only the physician making or establishing the finding can make the affirmative statement that the qualifying symptoms did not exist before the date of your first implantation or that your scleroderma is not localized scleroderma.

**24. How can my current physician provide the affirmative statement that my qualifying symptoms did not exist before the date of first implantation without having known me before I had breast implants?**

This statement can be based upon patient history or review of existing medical records. If it is based upon patient history, it must be consistent with the medical records in the physician's possession. In addition, the Claims Office must receive a copy of the complete patient history taken by the physician.

### SECTION 3 MAJOR CRITERION

**25. What is the Major Criterion of Scleroderma?**

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 BCR records that physical examination of the patient revealed scleroderma skin thickening, and adequately describes the parts of the body where that thickened skin is found

**26. What does proximal mean?**

Proximal refers to an area of the body that is nearest the center or point of attachment. An example of a proximal body part is: The elbow is proximal to the wrist.

**27. I have scleroderma and my doctor described my skin as indurated. What does this mean?**

With scleroderma, the area of induration will appear as hardened tissue.

**28. What part of the body are the metacarpophalangeal joints and metatarsophalangeal joints?**

The metacarpophalangeal (MCP) joint is where the fingers attach to the hand. The metatarsophalangeal (MTP) joint is where the toes attach to the foot.

**29. I have scleroderma and the skin of my chest and upper back is thickened. Is this area considered the thorax?**

Yes. The thorax is the part of the body between the base of the neck and the diaphragm. This includes both the front (anterior) and the back (posterior) of the body.

### SECTION 4 MINOR CRITERIA

**30. What are Minor Criteria of Scleroderma?**

In the Revised Settlement Program, minor criteria of Scleroderma include:

1. Sclerodactyly: Symmetric thickening, tightening and induration of the skin 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; and
3. Bibasilar pulmonary fibrosis: Bilateral reticular pattern of linear or lineonodular densities most pronounced in basilar portions of the lungs on standard chest x-ray; may assume appearance of diffuse mottling or "honeycomb lung." These changes should not be attributable to primary lung disease.

31. **Will I be compensated with a diagnosis of CREST syndrome?**

No. CREST stands for calcinosis, Raynaud's phenomenon, esophageal dysmotility, sclerodactyly and telangiectasis. Sclerodactyly is one of the three minor criteria and is the only part of CREST syndrome that may be credited for SS.

32. **My doctor told me I have sclerodactyly. What is sclerodactyly?**

Sclerodactyly is scleroderma of the digits (fingers and/or toes). Clinically the skin over these areas becomes tight, stretched, smooth and hard.

33. **I only have sclerodactyly. Is this symptom enough to receive payment?**

No. Sclerodactyly alone is not enough to meet any compensation level.

34. **I have a diagnosis of SS and my medical records state that I have depressed areas on the ends of my fingers. Will this meet as one of the minor criteria?**

Yes. In addition, other possible descriptions for digital pitting scars or loss of substance from the finger pads include a loss of substance, erosions, atrophy, ischemic ulcers and loss of digital pad.

35. **How is bibasilar pulmonary fibrosis diagnosed?**

Bibasilar pulmonary fibrosis is diagnosed on chest x-ray (chest roentgenogram).

## SECTION 5 COMPENSATION LEVELS

36. **How is compensation level A defined?**

Death resulting from systemic sclerosis/scleroderma (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.

37. **My wife is a deceased claimant. What legal paperwork do I need to submit so that my wife's estate can be paid?**

Along with either a death certificate that reflects SS as a cause of death or medical records reflecting severe renal involvement that meet criteria, Exhibit E1 requires that the representative for the estate be court appointed. However, if your wife's estate has no debts then a completed affidavit of heirship may be satisfactory. No benefits can be paid until the Claims Office receives documentation of a Court Appointed Representative or submission of an Affidavit of Heirship available from the Claims Office or on the website at [www.claimoffice-926.com](http://www.claimoffice-926.com).

38. **What is the standard used by the Claims Office for determining the age and gender adjusted norm?**

The Claims Office uses Dr. E. Koushanpour's textbook of *Renal Physiology, Principals, Structure, and Function, Second Edition*, Table 7.1, which measures serum creatinine

concentration, urinary creatinine excretion, and endogenous creatinine clearance in adult men and women at different age groups.

**39. What medical records do I need to support my chronic renal involvement?**

You need to send to the Claims Office the laboratory report reflecting the 24-hour urine specimen, along with all of your medical records supporting your scleroderma and chronic renal involvement.

**40. My wife had a diagnosis of scleroderma and is deceased. Her death certificate states scleroderma as a secondary cause of death. Is this enough for her estate to be paid for Compensation Level A?**

Along with the supporting medical records reflecting scleroderma, level A compensation, on the basis of death resulting from systemic sclerosis/scleroderma (SS), may be credited if either the death certificate reflects SS or one of the claimant's credited SS symptoms is listed as the cause of death, either primary or secondary. In addition, if the claimant's medical records reflect SS, one of her credited symptoms, or complications from SS as a cause of her death, this may satisfy the criteria for level A compensation.

**41. How is compensation level B defined?**

Clinically significant cardio-pulmonary manifestations of scleroderma as manifested by:

1. Interstitial fibrosis based upon physical examination findings AND abnormalities seen on chest x-ray or chest CT, or
2. Pulmonary hypertension based upon physical examination findings AND 2-D Echo Doppler or angiography with hemodynamic measurements showing pulmonary pressures of greater than 25 TORR, or
3. Proximal scleroderma on the trunk (thorax and abdomen).

**42. What are some physical exam findings reflecting interstitial fibrosis?**

Examples of the symptoms of interstitial fibrosis include breathlessness, non-productive cough, diffuse rales and rhonchi, depressed lung volume and diffusion capacity, resting hypoxia with mild hypocapnia and exercise-induced impairment of gas exchange.

**43. What are some physical exam findings reflecting pulmonary hypertension?**

Physical exam findings supporting pulmonary hypertension include right-sided heart failure, fatigue, chest discomfort, tachypnea and dyspnea (particularly with exercise).

**44. How is compensation level C defined?**

A diagnosis of scleroderma in accordance with the criteria contained in Exhibit E1 that does not involve the findings of compensation level A or B. If you have a diagnosis of scleroderma and either the major criterion or at least two of the minor criteria, but do not meet the criteria for compensation level A or B, you will qualify for compensation level C. As stated above, Exhibit E1 is available by calling the Claims Office or visiting the Claims Office website at [www.claimsoffice-926.com/pdf/mdl926\\_exhibit\\_E1.pdf](http://www.claimsoffice-926.com/pdf/mdl926_exhibit_E1.pdf).