

SUPPORTING MEDICAL DOCUMENTATION FORM

**DOW CORNING/BRITISH COLUMBIA AND OTHER PROVINCES
BREAST IMPLANT LITIGATION SETTLEMENT**

Note: Supporting medical documentation must be submitted with your Rupture, Current or Ongoing claim. If you are making a Current claim and/or a Rupture claim, your supporting medical documentation must be submitted on or before December 1, 2004. If you are making an Ongoing claim, your supporting documentation must be submitted on or before June 1, 2009.

This form has been created to assist claimants in completing their claim with respect to Supporting Medical Documentation and their Designated Medical Condition. This form is not a mandatory component of a claim. Further, this form does not supercede the need to submit physician reports, examination reports, test results and other supporting documentation required by the agreement

This form may be completed on-line at www.canadianbreastimplantsettlement.com

**THE INFORMATION PROVIDED IN THIS FORM WILL REMAIN CONFIDENTIAL
EXCEPT AS PROVIDED FOR IN THE BRITISH COLUMBIA AND OTHER
PROVINCES BREAST IMPLANT LITIGATION SETTLEMENT
AGREEMENT (“Agreement”)**

Please mail this form to:
Claims Administrator
c/o Deloitte & Touche LLP
PO Box 48660
Vancouver, B.C.
Canada
V7X 1A3

IDENTIFICATION OF CLAIMANT/SETTLEMENT CLASS MEMBER

BC Registration Number:	Date of Birth:		
	Day	Month	Year
Surname:	First Name:	Middle Name:	

This form summarizes elements of the Agreement relating to Designated Medical Conditions/Diagnoses and Supporting Medical Documentation.

In the event of contradiction between this form and the Agreement, the Agreement shall govern.

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INSTRUCTIONS TO CLAIMANTS and PHYSICIANS:

This form is provided to assist claimants and/or their physicians on what Supporting Medical Documentation is and what Designated Medical Conditions are, as listed in the Agreement. All claimants filing a Current, Rupture or an Ongoing Claim need to submit Supporting Medical Documentation, as detailed in the Agreement, to the Claims Administrator at the time of filing the claim.

Current or Ongoing Claim

Supporting Medical documentation for a Current or Ongoing Claim consists of:

A clinical diagnosis made by an appropriate “Licensed Medical Specialist”(“LMS”) who is:

- a Fellow of the Royal College of Physicians and Surgeons;
- a Canadian board-certified specialist; or
- a certified specialist from another country, (acceptable to the Claims Administrator) in a relevant medical specialty, as determined appropriate by the Claims Administrator

AND

where applicable pursuant to the Medical Conditions List, a statement of disability must be provided by the Claimant’s treating physician who has performed a disability examination and evaluation on the Claimant.

Should you choose to use this form, it should be submitted together with the physician reports, examination reports and test results on which the diagnosis is based, which will enable the Claims Administrator to place the Eligible Claimant within a category on the Medical Conditions List.

As part of the claim, whether a Current or Ongoing claim, the LMS must indicate the diagnosed Designated Medical Condition, on behalf of the Claimant, from the following options:

- Option I; or
- Option II.

If a Claimant is making a Current or Ongoing Claim, please note that only one diagnosis may be designated. This designation is based on the clinical diagnosis, made by an appropriate LMS, of a Designated Medical Condition; depending on which category the Designated Medical Condition falls into. The following pages list the applicable Designated Medical Conditions and provide guidelines on the diagnosis of each condition. Within Options I and II, the LMS or treating physician, where applicable, must also indicate the severity of the diagnosis (e.g. Levels A-D). Settlement criteria with respect to the severity/disability category are also listed on the following pages.

If a Claimant, at the time of submission of a claim, meets the eligibility requirements for more than one Designated Medical Condition, they will be entitled to receive the amount of compensation applicable only to the most highly compensated medical condition (i.e. highest ratio) for which they meet the eligibility requirements.

Rupture Claim

Supporting Medical Documentation for Rupture shall consist of contemporaneous operative reports or pathology reports demonstrating that the Claimant has had a Rupture of one or more Dow Corning Breast Implants.

A Rupture claim may be made either alone, or together with a Current Claim or an Ongoing Claim. Page twenty-two (22) of the form provides guidelines with respect to making a Rupture Claim.

A copy of the Compensation Schedule, Exhibit A-1 of the Agreement, which provides the ratios allocated to the various Designated Medical Conditions, is provided below.

Extract from Exhibit A-1, Dow Corning/British Columbia and Other Provinces Breast Implant Litigation Settlement Agreement

COMPENSATION SCHEDULE

DESIGNATED MEDICAL CONDITION	Severity/Disability Category	Ratio or Amount
Option I	A	5
	B	2
	C&D	1
Option II	Scleroderma/Lupus – A	25
	Scleroderma/Lupus – B	20
	Scleroderma/Lupus – C	15
	GCTS/PMDM – A	11
	GCTS – B	7.5
Rupture	N/A	2

NOTE: Compensation for Rupture may be added to any claim under Option I or Option II of this Compensation Schedule.

This form summarizes elements of the Agreement relating to Designated Medical Conditions/Diagnoses and Supporting Medical Documentation.

In the event of contradiction between this form and the Agreement, the Agreement shall govern.

PHYSICIAN QUALIFICATIONS

Due to the nature of the Agreement that was reached between Dow Corning et al and the Class Counsel, on behalf of the plaintiff’s, the Claims Administrator needs to verify the qualifications of each physician. Accordingly, the following questions are posed to permit the Claims Administrator to properly address the qualifications of the physician(s) completing the form.

IDENTIFICATION OF LMS MAKING DIAGNOSIS/COMPLETING THIS FORM	
Surname:	First Name:
Fellow of the Royal College of Physicians and Surgeons	Yes <input type="checkbox"/> Number: _____ No <input type="checkbox"/>
Canadian Board-Certified Specialist	Yes <input type="checkbox"/> Number: _____ No <input type="checkbox"/>
Field(s) of Certification: _____ _____	Number: _____ Number: _____ Number: _____
Certified Specialist from another country: Field(s) of Certification: _____ & country certification obtained _____	Yes <input type="checkbox"/> No <input type="checkbox"/> Number: _____ Number: _____ Number: _____
As the Physician completing this form did you rely on a report or diagnosis of another physician?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Signature of LMS making this diagnosis:	

This form may be completed on-line at www.canadianbreastimplantsettlement.com The on-line version of this form will guide physicians through the form to ensure all required information is provided. The on-line form is also designed to minimize the time taken to complete the form.

Physicians may also register at the website. Registered physicians will only be required to submit their contact details and their qualifications once.

IDENTIFICATION OF TREATING PHYSICIAN GIVING STATEMENT OF DISABILITY
(Where applicable)

Surname:	First Name:
Fellow of the Royal College of Physicians and Surgeons	Yes <input type="checkbox"/> Number: _____ No <input type="checkbox"/>
Canadian Board-Certified Specialist	Yes <input type="checkbox"/> Number: _____ No <input type="checkbox"/>
Field(s) of Certification: _____ _____ _____	Number: _____ Number: _____ Number: _____
Certified Specialist from another country: Field(s) of Certification: _____ & country certification obtained _____ _____	Yes <input type="checkbox"/> No <input type="checkbox"/> Number: _____ Number: _____ Number: _____
Signature of Treating Physician giving Statement of Disability:	

This form may be completed on-line at www.canadianbreastimplantsettlement.com The on-line version of this form will guide physicians through the form to ensure all required information is provided. The on-line form is also designed to minimize the time taken to complete the form.

Physicians may also register at the website. Registered physicians will only be required to submit their contact details and their qualifications once.

OPTION I - DESIGNATED MEDICAL CONDITIONS

Diagnosis: ATYPICAL CONNECTIVE TISSUE DISEASE ("ACTD"), ATYPICAL RHEUMATIC SYNDROME ("ARS") AND NONSPECIFIC AUTOIMMUNE CONDITION ("NAC")

(Settlement Reference – Exhibit A-2, Part A, 7)

Yes

No

Criteria:

1. This category will provide compensation for 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 definitions 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 misdiagnosed 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. Compensation levels and eligibility criteria for eligible claimants are set forth in Exhibits A-1 and D to the Agreement, and classify individual claimants in accordance with the following groups of symptoms. If the claimant's Licensed Medical Specialist 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 Administrator 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 of the following sets of criteria:
 - i any two of the three signs and symptoms listed in Subparagraph 5(i), below (Group I);
 - ii any one of the three signs and symptoms listed in Subparagraph 5(i), below (Group I), plus any one of the ten signs and symptoms listed in Subparagraph 5(ii), below (Group II);
 - iii any three of the ten signs and symptoms listed in Subparagraph 5(ii), below (Group II);
 - iv any two of the ten signs and symptoms listed in Subparagraph 5(ii), below (Group II), plus any one additional (nonduplicative) sign or symptom from the eighteen listed in Subparagraph 5(iii), below (Group III); or
 - v five nonduplicative signs or symptoms listed in Subparagraphs 5(i) (Group I), 5(ii) (Group II) or 5(iii) (Group III), below;
5. Symptom Groupings
 - i Group I Signs and Symptoms
 - a Raynaud's phenomenon evidenced by the patient giving a history of two color changes, or visual evidence of vasospasm, or evidence of digital ulceration
 - b Polyarthritis, defined as synovial swelling and tenderness in three or more joints lasting greater than six weeks and observed by a physician
 - c Keratoconjunctivitis Sicca: subjective complaints of dry eyes and/or dry mouth, accompanied by any one of the following:
 - lacrimal or salivary enlargement
 - parotid enlargement
 - abnormal Schirmer test
 - abnormal Rose-Bengal staining
 - filamentous keratitis
 - abnormal parotid scan or ultrasound
 - abnormal CT or MRI of parotid
 - abnormal labial salivary biopsy
 - ii Group II Signs and Symptoms
 - a Myalgias determined by tenderness on examination
 - b Immune mediated skin changes or rash, as follows:

Diagnosis: ATYPICAL CONNECTIVE TISSUE DISEASE ("ACTD"), ATYPICAL RHEUMATIC SYNDROME ("ARS") AND NONSPECIFIC AUTOIMMUNE CONDITION ("NAC")

(Settlement Reference – Exhibit A-2, Part A, 7) (Continued from page 5)

- 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;
 - c 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., decrease DLCO or abnormal arterial blood gases)
 - d pericarditis defined by consistent clinical findings and either EKG or echocardiogram;
 - e 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;
 - f peripheral neuropathy diagnosed by physical examination showing one 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, or
 - entrapment neuropathies.
 - g 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;
 - h Serologic abnormalities -- include any one of the following:
 - ANA > than 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, antimicrosomal, 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
 - i Lymphadenopathy (as defined by at least 1 lymph node greater than or equal to 1x1 cm) documented by a physician
 - j Dysphagia with positive cine-esophagram, manometry or equivalent imaging.
- iii Group III Signs and Symptoms
 - a Documented arthralgia
 - b Documented Myalgias
 - c Chronic fatigue
 - d Lymphadenopathy
 - e Documented Neurological symptoms including cognitive dysfunction or paresthesia
 - f Photosensitivity
 - g Sicca symptoms
 - h Dysphagia
 - i Alopecia
 - j Sustained balance disturbances
 - k Documented sleep disturbances
 - l Easy bruisability or bleeding disorder
 - m Chronic cystitis or bladder irritability

Diagnosis: ATYPICAL CONNECTIVE TISSUE DISEASE ("ACTD"), ATYPICAL RHEUMATIC SYNDROME ("ARS") AND NONSPECIFIC AUTOIMMUNE CONDITION ("NAC")

(Settlement Reference – Exhibit A-2, Part A, 7) (Continued from page 6)

- n Colitis or bowel irritability
- o Persistent low grade fever or night sweats
- p Mucosal ulcers confirmed by physician
- q Burning pain in the chest, breast, arms, or axilia, or substantial loss of function in breast due to disfigurement or other complications from implants or explanation
- r Pathological findings of granulomas or siliconomas or chronic inflammatory response or breast infections

Severity/Disability Category:

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 ¹, avocational ² or usual self-care activities³. In evaluating the effect of the 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.

Category 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 avocation or self-care.

Category B

A claimant will be eligible for Category B compensation if she is 35 percent disabled due to the compensable condition. An individual shall be considered 35 percent 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.

Category C

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

Documents being provided to support Diagnosis and Severity/Disability Category:

¹ "Vocational" means activities associated with work, school and homemaking.

² "Avocational" means activities associated with recreation and leisure.

³ "Usual self-care" means activities associated with dressing, feeding, bathing, grooming and toileting.

Diagnosis: SYSTEMIC SCLEROSIS/SCLERODERMA ("SS")

(Settlement Reference – Exhibit A-2, Part A, 1)

Yes

No

Criteria:

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.

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 SS 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.

Severity/Disability Category:

Category 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.

Category 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).

Category C

Other, including CREST, limited, or intermediate scleroderma; except that any claimant who manifests either severe renal involvement, as defined above, or cardio-pulmonary involvement, will be compensated at either Category A or Category B as appropriate.

Category D

Other not covered above, including localized scleroderma.

Documents being provided to support Diagnosis and Severity/Disability Category:

Diagnosis: SYSTEMIC LUPUS ERYTHEMATOSUS ("SLE")

Settlement Reference – Exhibit A-2, Part A, 2

Yes

No

Criteria:

1. A diagnosis of systemic lupus erythematosus ("SLE") shall be made in accordance with the "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 Kelly, et al., 4th ed. at 1037, Table 61-11: A diagnosis of lupus is made if four of the eleven 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 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 2 or more occasions or (c) Lymphopenia – less than 1500/mm on 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 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. 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.

Severity/Disability Category:

Category 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.

Category B

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

Category 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.

Category 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.

Documents being provided to support Diagnosis and Severity/Disability Category:

Diagnosis: ATYPICAL NEUROLOGICAL DISEASE SYNDROME ("ANDS")

(Settlement Reference – Exhibit A-2, Part A, 3)

Yes

No

Criteria:

2. A diagnosis of Atypical Neurological Disease Syndrome ("ANDS") shall be based on 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, rheumatic or nonspecific autoimmune signs and symptoms.
3. Eligibility for Atypical Neurological Disease Syndrome requires both:
 - i satisfying the requirements for one of the four neurological disease types set forth in Paragraph 5, below; and
 - ii any three additional (nonduplicative) neuromuscular, rheumatic or nonspecific symptoms or findings set forth in the definition for Atypical Connective Tissue Disease (ACTD).
4. An individual will fit into this category if her primary symptoms are characteristic of a neurological disease as diagnosed by a Licensed Medical Specialist certified in neurology or internal medicine.
5. If the individual's Licensed Medical Specialist 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 Administrator 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.
6. Neurological Disease Types
 - i 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:
 - a Objectively-demonstrated loss of sensation to pinprick, vibration, touch or position
 - b Proximal or distal muscle weakness
 - c Tingling and/or burning pain in the extremities
 - d Signs of dysesthesia
 - e Loss of tendon reflex;

Plus one or more of the following laboratory findings:

- f Abnormal levels of anti-mag or anti-sulfatide or anti-GM 1 antibodies;
 - g Abnormal sural nerve biopsy
 - h Abnormal electrodiagnostic testing (EMG or nerve conduction studies, etc.).
- ii 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 or more of the following signs and symptoms:
 - a Weakness in the pyramidal distribution
 - b Evidence of optic neuritis documented by ophthalmologist
 - c Increased deep tendon reflexes
 - d Absent superficial abdominal reflexes
 - e Ataxia or dysidiadochokinesia as the sign of cerebellar involvement
 - f Neurologically induced tremors
 - g Internuclear ophthalmoplegia and/or bladder or speech involvement secondary to central nervous system disease

Plus one or more of the following:

- h Abnormal Brain MRI with foci of increased signal abnormality suggestive of demyelinating lesions
- i Delayed visual-evoked responses or abnormal-evoked potentials
- j Abnormal CSF with olioclonal bands.

Diagnosis: ATYPICAL NEUROLOGICAL DISEASE SYNDROME ("ANDS") (Continued from page 11)
(Settlement Reference – Exhibit A-2, Part A, 3)

- iii ALS-Like Syndrome
This disease category requires documented evidence of progressive upper and widespread lower motor neuron disease and/or bulbar involvement, plus one or more of the following:
 - a Neurological autoantibodies such as anti-mag, anti-sulfatide or anti-GM-1
 - b Abnormal sural nerve biopsy
 - c Chronic inflammation on muscle or nerve biopsies
 - d Abnormal EMG
 - e Documentation on exam of both upper and lower motor neuron disease and/or bulbar involvement.

- iv Disease of Neuromuscular Junction
This disease category requires either (1) a diagnosis of Myasthenia Gravis or Myasthenia Gravis-like syndrome or disorders of NMJ, made by a Licensed Medical Physician certified in neurology 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.

Severity/Disability Category:

The compensation level for ANDS will be based on the degree to which the individual is "disabled" by the condition, as the individual's licensed 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 vocational⁴, avocational⁵ or usual self-care⁶ activities. In evaluating the effect of the individual's symptoms, the treating physician 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.

- Category 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.

- Category B
A claimant will be eligible for Category B compensation if she is 35 percent disabled due to the compensable condition. An individual shall be considered 35 percent 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 perform them only with regular or recurring severe pain.

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

Documents being provided to support Diagnosis and Severity/Disability Category:

⁴ "Vocational" means associated with work, school, and homemaking.
⁵ "Avocational" means associated with recreation and leisure.
⁶ "Usual self-care" means associated with dressing, feeding, bathing, grooming and toileting.

Diagnosis: MIXED CONNECTIVE TISSUE DISEASE ("MCTD") / OVERLAP SYNDROME
(Settlement Reference – Exhibit A-2, Part A, 4)

Yes

No

Criteria:

1. A diagnosis of Mixed Connective Tissue Disease ("MCTD") shall be based on the presence of clinical symptoms characteristic of two 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, 4th ed. at 1061.
2. "Overlap Syndrome" is defined as any one of the following three: (i) diffuse cutaneous scleroderma, (ii) limited cutaneous scleroderma, or (iii) Sine scleroderma, occurring concomitantly with diagnosis of systemic lupus erythematosus, inflammatory muscle disease, or rheumatoid arthritis. See Kelley, et al., Table 66-2, 4th ed. 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/nonspecific autoimmune condition.

Severity/Disability Category:

Category 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.

Category B

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

Category C

Other.

Documents being provided to support Diagnosis and Severity/Disability Category:

Diagnosis: POLYMYOSITIS/DERMATOMYOSITIS

(Settlement Reference – Exhibit A-2, Part A, 5)

Yes

No

Criteria:

1. A diagnosis of polymyositis or dermatomyositis shall be made in accordance with diagnostic criteria proposed by Bohan and Peter, "Polymyositis and Dermatomyositis," N.Engl. J. Med. 292:344, 1975, i.e., (i) symmetrical proximal muscle weakness, (ii) EMG changes characteristic of myositis including (a) short duration, small, low amplitude polyphasic potential, (b) fibrillation potentials, (c) bizarre high-frequency repetitive discharges, (iii) elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT and LDH), (iv) 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, (v) 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 the presence of three of the criteria plus the rash (fifth criterion). A diagnosis of polymyositis requires the presence of four criteria without the rash. See Kelley, et al., supra, 4th, ed. 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.

Severity/Disability Category:

Category 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.

Category B

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

Category C

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

Documents being provided to support Diagnosis and Severity/Disability Category:

Diagnosis: PRIMARY SJOGREN'S SYNDROME

(Settlement Reference – Exhibit A-2, Part A, 6)

Yes

No

Criteria:

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., supra, Table 55-1, 4th ed. 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.

Severity/Disability Category:

Category 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.

Category B

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

Category C

Other.

Documents being provided to support Diagnosis and Severity/Disability Category:

OPTION II - DESIGNATED MEDICAL CONDITIONS

General

(Settlement Reference – Exhibit A-2, Part B, 8)

1. A claimant must file with the Claims Administrator 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 of this Agreement). (Findings submitted in response to a deficiency letter sent by the Claims Administrator do not have to fall within the 24-month period outlined above.)

E.g. The five year period is calculated as follows for Current Claims:

Date of Submitting Claim	Aug 31/04	Sep 30/04	Oct 31/04	Nov 30/04
Effective Date of this Agreement	<u>Jun 01/04</u>	<u>Jun 01/04</u>	<u>Jun 01/04</u>	<u>Jun 01/04</u>
Total	3 Months	4 Months	5 Months	6 Months
5 Year Period Available	60 Months	60 Months	60 Months	60 Months
Less: Post Effective Date Time Used	<u>3 Months</u>	<u>4 Months</u>	<u>5 Months</u>	<u>6 Months</u>
Period available prior to May 15, 1995	57 Months	56 Months	55 Months	54 Months
Initial Date Available	Aug 15/90	Sept 15/90	Oct 15/90	Nov 15/90

E.g. The five year period is calculated as follows for Ongoing Claims:

Date of Submitting Claim	Aug 31/05	Aug 31/06	Aug 31/07	Aug 31/08
Effective Date of this Agreement	<u>Jun 01/04</u>	<u>Jun 01/04</u>	<u>Jun 01/04</u>	<u>Jun 01/04</u>
Total	15 Months	27 Months	39 Months	5 Months
5 Year Period Available	60 Months	60 Months	60 Months	60 Months
Less: Post Effective Date Time Used	<u>15 Months</u>	<u>27 Months</u>	<u>39 Months</u>	<u>5 Months</u>
Period available prior to May 15, 1995	45 Months	33 Months	21 Months	24 Months
Initial Date Available	Aug 15/91	Aug 15/92	Aug 15/93	Aug 15/94

2. 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 Administrator.
3. Statements by a Licensed Medical Specialist under Disease Payment Option II may be acceptable proof under that program if the Licensed Medical Specialist *is* certified in rheumatology – for Lupus, Scleroderma or Polymyositis/Dermatomyositis Claims – or the Licensed Medical Specialist is certified in the appropriate specialty to make the required GCTS findings, if the statement covers all of the detailed findings that are required in Disease Payment Option II, if the Licensed Medical Specialist personally examined the claimant, and if the doctor includes 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 II.
4. Claimants who seek benefits under Disease Payment Option II 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.

Diagnosis: SCLERODERMA(SS)
(Settlement Reference – Exhibit A-2, Part B, 9)

Yes No

Criteria:

1. A claim for scleroderma must include a diagnosis of systemic sclerosis/scleroderma made by a Licensed Medical Specialist certified in rheumatology based upon personal examination of the patient. [Exclusion; localized scleroderma.] Supporting Medical Documentation must affirmatively reveal that the major or at least two of the minor criteria listed below are present:

i 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 Licensed Medical Specialist certified in rheumatology 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.

ii Minor Criteria:

- a Sclerodactyly: Above-indicated skin changes limited to the fingers.
- b 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.
- c 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.

Severity/Disability Category:

- Category A
Death resulting from SS, or severe chronic renal involvement manifested by a glomerular filtration rate of less than 50 percent of the age- and gender-adjusted norm, as measured by an adequate 24-hour urine specimen collection.
- Category B
Clinically significant cardio-pulmonary manifestations of scleroderma⁷ or proximal scleroderma on the trunk (thorax and abdomen).
- Category C
A diagnosis of scleroderma in accordance with the above criteria that does not involve the findings in A or B above.

Documents being provided to support Diagnosis and Severity/Disability Category:

⁷ As manifested by interstitial fibrosis (based upon physical examination findings and abnormalities as seen on chest x-rays or chest CT) or pulmonary hypertension (based upon physical examination findings and 2-D Echo doppler or angiography with hemodynamic measurements showing pulmonary artery pressures of greater than 25 TORR).

Diagnosis: LUPUS (SLE)

(Settlement Reference – Exhibit A-2, Part B, 10)

Yes

No

Criteria:

- 1. A claim for SLE must include a diagnosis of SLE (lupus) made by a Licensed Medical Specialist certified in rheumatology 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 of the following 11 criteria are present:

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 [Exclusion: erosive arthritis]
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 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
Hematologic disorder	(a) Hemolytic anemia – with reticulocytosis or (b) Leukopenia – less than 4000/mm total on 2 or more occasions or (c) Lymphopenia – less than 1500/mm on 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 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

Severity/Disability Category:

Category A

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

Category B

SLE with involvement of one 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.

Category 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).

Documents being provided to support Diagnosis and Severity/Disability Category:

Diagnosis: POLYMYOSITIS (PM)/DERMATOMYOSITIS (DM)
(Settlement Reference – Exhibit A-2, Part B, 11)

Yes

No

Criteria:

1. A claim for polymyositis or dermatomyositis must include a diagnosis of the disease made by a Licensed Medical Specialist certified in rheumatology based upon personal examination of the patient. Supporting Medical Documentation must affirmatively reveal that the following criteria are present:
 - i for polymyositis, the first four criteria without the rash;
 - ii for dermatomyositis, three of the first four criteria, plus the rash (#5)
 - a symmetrical proximal muscle weakness;
 - b EMG changes characteristic of myositis including (a) short duration, small, low-amplitude polyphasic potential, (b) fibrillation potentials,
 - c bizarre high-frequency repetitive discharges;
 - d elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT and LDH);muscle biopsy showing evidence of necrosis of type I and II
 - e muscle fibers areas of degeneration and regeneration of fibers, phagocytosis and an interstitial or perivascular inflammatory response;
 - f 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.

Severity/Disability Category:

Category A

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

Documents being provided to support Diagnosis and Severity/Disability Category:

Diagnosis: GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS)

(Settlement Reference – Exhibit A-2, Part B, 12)

Yes

No

Criteria:

1. 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.]
2. In addition to the medical verification of the required findings, a claim for GCTS must include the affirmative physician statements outlined in the "General" Section above.

Severity/Disability Category:

Category A

- i any two findings from Group I; or
- ii any three non-duplicative findings from Group I or Group II.

(PLEASE CIRCLE THE NUMBER OF THE RELEVANT FINDINGS BELOW)

Category B

- i one finding from Group I plus any four non-duplicative findings from Group II or Group III; or
- ii two findings from Group II plus one non-duplicative finding from Group III.

(PLEASE CIRCLE THE NUMBER OF THE RELEVANT FINDINGS BELOW)

The following duplications exist on the list of findings:

- o rashes(iii) and (viii)
- o sicca (ii) and (xii)
- o serological abnormalities (iv) and (ix)

GROUP I FINDINGS

- (i) Polyarthrititis, defined as synovial swelling and tenderness in three or more joints in at least two different joint groups observed on more than one physical examination by a Licensed Medical Specialist and persisting for more than six weeks. [Exclusion: osteoarthritis.]
- (ii) 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 based upon average of four evaluable lobules). [Exclusions: drugs known to cause dry eyes and/or dry mouth, and dry eyes caused by contact lenses.]
- (iii) Any of the following immune-mediated skin changes or rashes, observed by a Licensed Medical Specialist certified in rheumatology or dermatology; (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

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

Diagnosis: GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS) (Continued from page 20)
(Settlement Reference – Exhibit A-2, Part B, 12)

- (v) Abnormal cardiopulmonary symptoms, defined as (a) pericarditis documented by pericardial friction rub and characteristic echocardiogram findings (as reported by a Licensed Medical Specialist certified in radiology or cardiology); (b) pleuritic chest pain documented by pleural friction rub on exam and chest x-ray diagnostic of pleural effusion (as reported by a Licensed Medical Specialist certified in radiology); or (c) interstitial lung disease in a non-smoker diagnosed by a Licensed Medical Specialist certified in pulmonology or internal medical, confirmed by (i) chest x-ray or CT evidence (as reported by a Licensed Medical Specialist certified in radiology) and (ii) pulmonary function testing abnormalities defined as decreased DLCO less than 80 percent of predicted.
- (vi) Myositis or myopathy, defined as any two 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 separate occasions at least six weeks apart. (If the level of the initial test is three times normal or greater, one test would be sufficient.) [Exclusions: injections, trauma, hypothyroidism, prolonged exercise or drugs known to cause abnormal CPK or aldolase]; or (c) muscle biopsy (at the 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.
- (vii) Peripheral neuropathy or polyneuropathy, diagnosed by a Licensed Medical Specialist certified in neurology, 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 months preceding the diagnosis.]

GROUP III FINDINGS

- (viii) Other immune-mediated skin changes or rashes, observed by a Licensed Medical Specialist certified in rheumatology or dermatology: (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.
- (ix) Any of the following serologic abnormalities: (a) ANA greater than or equal to 1:40 (using Hep2) on two separate occasions separated by at least two months; (b) one 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-mitochondrial, anti-cardiolipin or RF greater than or equal to 1:80.
- (x) Raynaud's phenomenon, evidenced by a physician-observed two (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.
- (xi) Myalgias, defined as tenderness to palpation, performed by a physician, in at least three muscles, each persisting for at least six months.
- (xii) 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.]

Documents being provided to support Diagnosis and Severity/Disability Category:

RUPTURE CLAIM

Rupture of a Dow Corning Breast Implant

Yes

No

Criteria:

A "Rupture" refers to the failure of the elastomer envelope surrounding a silicone-gel breast implant to contain the gel (resulting in contact of the gel with the body), not solely as a result of "gel bleed," but due to a tear or other opening in or significant disintegration of the envelope after implantation and prior to the explanation procedure.

Severity/Disability Category:

No Severity/Disability Compensation Categories are applicable to Rupture.

Documents being provided to support Rupture Claim:

This form summarizes elements of the Agreement relating to Designated Medical Conditions/Diagnoses and Supporting Medical Documentation.

In the event of contradiction between this form and the Agreement, the Agreement shall govern.