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CLAIMS OFFICE
MDL-926 REVISED BREAST IMPLANT SETTLEMENT
P. O. BOX 56666
HOUSTON, TEXAS 77256
www.claimsoffice-926.com

Telephone Number: 800/600-0311

QUESTIONS AND ANSWERS ABOUT SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

The questions and answers in this pamphlet address many issues important to claimants making a claim for benefits for Systemic Lupus Erythematosus (SLE).

Section 1 **General Questions**
Section 2 **Exclusions and Affirmative Statements**
Section 3 **Criteria (11)**
1. **Malar rash**
2. **Discoid rash**
3. **Photosensitivity**
4. **Oral Ulcers**
5. **Arthritis**
6. **Serositis**
7. **Renal disorder**
8. **Neurologic disorder**
9. **Hematologic disorder**
10. **Immunologic disorder**
11. **Antinuclear antibody**

Section 4 **Compensation Levels**

SECTION 1 GENERAL QUESTIONS

Q1-1 Where can I find the exact criteria for Systemic Lupus Erythematosus?

A Read Exhibit E1, specifically: Section 1. General, , and Section III, Lupus (SLE). Read it carefully and completely.

Q1-2 Where can I get a copy of Exhibit E1?

A 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.

Q1-3 What should I submit to support my SLE claim?

A You should submit all underlying medical records that may establish your required criteria or laboratory abnormalities. As such, please send any additional medical records you may have supporting your SLE diagnosis and symptoms to the Claims Office including all underlying office charts, radiology/pathology reports and laboratory test results from any health care professional that provided you with medical care. Examples of health care professionals include the following:

Medical Doctors (MD)
Doctors of Osteopathy (DO)
Chiropractors
Podiatrists
Dentists
Nurse Practitioners
Optometrists
Occupational Therapists
Physician Assistants
Physical Therapists
Pharmacists

In addition, please note that a claim for SLE must include a **diagnosis** of SLE made by a **board-certified rheumatologist (BCR) based upon personal physical examination of the patient.** Supporting medical documentation must affirmatively reveal that at least four (4) of the eleven (11) criteria are present.

Note that claimants with Mild Lupus/SLE not requiring regular medical attention, including doctor visits and regular prescription medication, are not entitled to benefits under the settlement.

Q1-4 Can my physician write a letter to summarize my symptoms?

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

Q1-5 My physician stated that I have SLE, documented more than four symptoms and made 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?

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

Q1-6 What is the five (5) year time frame?

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

Q1-7 What is the twenty-four (24) month time frame?

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

Q1-8 How do I get a phone call from a Claims Officer to discuss my claim?

A 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.

Q1-9 How do I get a re-review of my claim?

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

Q1-10 Where do I get these forms?

A All forms and information concerning the settlement can be obtained by calling 1-800-600-0311. In addition, they may be obtained from the Claims Office website at www.claimsoffice-926.com either on the home page or under the Forms tab.

Q1-11 How long do I have to send in additional information about my claim?

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

Q1-12 Do I have to correct all the deficiencies in my SLE letter?

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

Q1-13 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?

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

SECTION 2 EXCLUSIONS AND AFFIRMATIVE STATEMENTS

Q2-1 What is an exclusion for SLE (Lupus)?

A An exclusion is a condition that may exist which could disqualify a claimant from qualifying for compensation for SLE (lupus) or a symptom thereof.

Q2-2 What is an exclusion statement and who can provide this statement?

A The exclusion statement is a required written statement by the BCR who establishes the diagnosis. Please note that merely stating "the exclusion is not present" is not sufficient because each exclusion must be specifically mentioned.

Q2-3 Where are the exclusion explained?

A The general exclusion that your symptoms did not exist before your first implantation is contained in paragraph III(B) of Exhibit E1. The general exclusion for lupus is set apart by brackets in the first paragraph of the SLE definition as noted in paragraph III of Exhibit E1. In addition, the exclusion for the SLE symptom of arthritis is set apart by brackets in the definition of the criterion for arthritis in paragraph III(B) of Exhibit E1. Exhibit E1 is available by calling the Claims Office or visiting the Claims Office website at www.claimsoffice-926.com.

Q2-4 What is the exclusion for mild lupus?

A The settlement defines mild lupus as "SLE not requiring regular medical attention including doctor visits and regular prescription medications."

Q2-5 What if the BCR states that I have "mild" lupus because I do not have major organ involvement—will this prevent me from qualifying from SLE?

A Not necessarily. Your doctor's definition of "mild" SLE and the settlement's definition may differ. [See Q2-4.]

Q2-6 What if I cannot or do not take prescription medications for my lupus—can I still qualify?

A Lupus, as set forth in Exhibit E1, requires regular medical attention, including doctor visits and regular prescription medications.

Q2-7 What is meant by the phrase affirmatively state that the qualifying lupus symptoms did not exist before the date of first implantation?

A Lupus requires the **BCR** to specifically state that your lupus symptoms did not exist before your first breast implantation. Additionally, Exhibit E1 requires that these physician's statements be written affirmatively. For example, a statement that your "lupus" was not pre-existing will generate a deficiency for two reasons: (1) the statement is not in the affirmative; and (2) the statement indicates that the Lupus, rather than the Lupus symptoms did not exist before your first breast implantation.

Q2-8 Who can make the affirmative statement?

A For SLE, only the BCR making the diagnosis can make the affirmative statement that the qualifying lupus symptoms did not exist before the date of your first implantation.

Q2-9 How can my current rheumatologist provide this affirmative statement without having known me before I had breast implants?

A This statement can be based upon patient history or review of existing medical records as long as it is 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. The Claims Office will review your medical records to determine if the exclusion has been addressed.

SECTION 3 Systemic Lupus Erythematosus (SLE) CRITERIA:

Q3-1 What symptoms must I have in order to qualify for compensation for lupus?

A Supporting medical documentation must reveal that at least four (4) of the eleven (11) criteria are present.

Q3-2 What is a "diagnosis" of SLE (Lupus)?

A A diagnosis is an identification by a physician of a particular disease or condition, based on the patient's signs and symptoms. The term "diagnosis" does not need to be used so long as it is clear that an actual diagnosis has been reached. For example, a clear-cut statement that you indeed have lupus will suffice. Please note that phrases like "may have," "possible lupus," "lupus-like," and "lupus syndrome" are not the equivalent of a diagnosis.

The Revised Settlement Program requires that four (4) of the eleven (11) listed SLE criteria are present to support that diagnosis, but the existence of four (4) or more of those criteria cannot substitute for the diagnosis itself. For that reason, a letter saying you meet four (4) or more of those criteria and thus qualify for SLE under the revised disease criteria will not be sufficient. The **BCR** must do more than say you meet the listed criteria. He or she must actually conclude and affirmatively state that you suffer from SLE. Then and only then will the Claims Officers review the supporting medical documentation to see if the required confirming criteria are present.

Q3-3 My family doctor, who is my treating physician, told me that I have lupus. Can (s)he make this diagnosis?

A No. The settlement requires the diagnosis of lupus be made by a **BCR** based on personal exam.

Q3-4 What physician can establish my SLE symptoms?

A Any treating physician can document your SLE symptoms, however, the BCR must acknowledge those symptoms as supporting your diagnosis of SLE.

Q3-5 What is a malar rash?

A Exhibit E1 defines the SLE criterion for malar rash as: "fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds." This rash generally appears as a reddish facial eruption over the bridge of the nose and cheeks, resembling a butterfly in flight.

Q3-6 My malar rash is sensitive to the sun—can I qualify for both malar rash and photosensitivity?

A We cannot credit both malar rash and photosensitivity when a physician states that a malar rash is "extremely sun-sensitive or photosensitive" because malar rash is a photosensitive rash. In order to credit both malar rash and photosensitivity, you must have documentation of a skin rash as a result of sun exposure occurring on an area other than the face.

Q3-7 What is photosensitivity?

A Exhibit E1 defines photosensitivity as: "skin rash as the result of unusual reaction to sunlight, by patient history or physician observation." (Please note, photophobia, refers to light sensitivity of the eyes and it not the same thing as a photosensitivity reaction.)

Q3-8 What is a discoid rash?

A Exhibit E1 defines discoid rash as: "erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions."

Q3-9 When I go outside into the sun, my joints ache and I sometimes feel sick and very fatigued. Does this count for photosensitivity?

A No. Although many lupus patients complain of increased joint pain, feeling ill and increased fatigue with sun exposure, we can only credit photosensitivity that is manifested by an actual skin rash as a result of sun exposure.

Q3-10 Will my history of oral ulcers be sufficient documentation to credit oral ulcers?

A No. Exhibit E1 requires that your ulcers be observed by a physician.

Q3-11 What are peripheral joints?

A The "peripheral joints" include the shoulders, hips, feet, toes, ankles, elbows, hands and fingers. Exhibit E1 requires that two or more joints be characterized by tenderness, swelling, or effusion.

Q3-12 What does the exclusion for erosive arthritis mean? Do I need x-rays?

A The physician who finds your arthritis must make an affirmative statement that your arthritis is non-erosive. He or she may choose to take x-rays, but the settlement does not require this. For example, rheumatoid arthritis may be an erosive type of arthritis in which there is joint destruction as the result of an inflammatory process and this type of arthritis generally cannot be credited.

Q3-13 My doctor says I have arthralgias—is this enough to be credited with arthritis?

A No. Arthralgia simply means joint pain. The settlement requires that you have arthritis, not merely arthralgias.

Q3-14 My doctor listed serositis as one of my lupus symptoms, what are pleuritis and pericarditis?

A Pleuritis means inflammation of the membranous covering of the lungs. Pericarditis refers to an inflammatory process involving the membranous sac surrounding the heart.

Q3-15 I'm having chest pain, can this qualify me for pleuritis?

A Not necessarily. Chest pain can be the result of many factors. To qualify for pleuritis your medical records need to reflect that your chest pain is related to your lungs.

Q3-16 To what does the phrase a "convincing history of pleuritic pain" refer?

A As noted above, there are many causes of chest pain, e.g. ., indigestion, muscle strain, cardiovascular disease, etc. However, symptoms related to pleuritic chest pain are generally specific and relate to your lungs. Many times this is a recurring finding.

Q3-17 What medical records do I need to support Renal disorder?

A You will need a laboratory report reflecting a urinalysis that shows an elevated amount of protein or the presence of cellular casts.

Q3-18 Will a urinalysis result that shows 2+ proteinuria meet settlement criteria?

A No. Exhibit E1 requires 0.5 grams per day or greater than 3+ protein in the urine. Because Exhibit E1 requires "persistent" proteinuria, a one time notation of increased protein in the urine is not sufficient. Therefore, you must submit documentation of more than one urinalysis result that meets settlement criteria.

Q3-19 What are cellular casts?

A Cellular casts are a part of a urinalysis lab report. Types of cellular casts include red cells, granular, tubular, mixed, and hemoglobin.

Q3-20 I have a seizure disorder; will this meet the criteria?

A Exhibit E1 defines the neurologic disorder as: Seizures -- in the absence of offending drugs or known metabolic derangements, e. g., uremia, ketoacidosis, or electrolyte imbalance.

It is important to understand that your seizure disorder must be a result of your lupus. In addition, the word "seizures" is plural; therefore, your medical records must reflect that you have had more than one seizure. Furthermore, Exhibit E1 specifically requires that your seizure disorder be in the ABSENCE of offending drugs or known metabolic derangements. For example, a person who abruptly stops taking a medication could have a seizure as a result of suddenly discontinuing the medication, but the seizures are not due to lupus. In addition, many electrolyte disturbances can result in a seizure that is not due to lupus. Many patients with this neurologic disorder will have had some diagnostic testing such as a CAT scan and/or an EEG (electroencephalogram). Also, most lupus patients with a seizure disorder will require daily anticonvulsant medication.

Q3-21 My physician says I have lupus induced psychosis which should qualify as a neurologic disorder of lupus. Can you credit it?

A No. Exhibit E1 only permits seizures as the credited finding for neurologic disorder. However, lupus psychosis may be used to increase your compensation level. [See Q4-8.]

Q3-22 What is a Hematologic disorder?

A Exhibit E1 defines this as:

a) Hemolytic anemia – with reticulocytosis, or
b) Leukopenia – less than 4,000/mm total on two or more occasions, or

c) Lymphopenia – less than 1,500/mm on two or more occasions, or
d) Thrombocytopenia – less than 100,000/mm in absence of offending drugs.

a) **Hemolytic anemia** is a reported decrease in the red blood cell (RBC), hemoglobin (Hgb) and hematocrit (Hct). Reticulocytosis is an increase in the number of reticulocytes (immature red blood cells) in the blood accompanied by hemolytic anemia. To count this symptom, the reticulocyte count must be included in the records with the complete blood count (CBC). Therefore, we would need your lab reports that reflect a decreased RBC, Hgb and Hct as well as an elevated reticulocyte count.

b) **Leukopenia** is an abnormal decrease in the number of white blood cells (WBC) circulating in the blood. This is evident as the WBC on the lab reports. Exhibit E1 requires that the total WBC count be less than 4000 on two or more occasions.

c) **Lymphopenia** is a decrease in the proportion of lymphocytes in the blood. Standard labs report lymphocytes in two different ways, either as a percentage of the WBC or as a lymphocyte count. Exhibit E1 requires that the lymphocyte count be less than 1500 on two or more occasions.

d) **Thrombocytopenia** is a decrease in the number of platelets circulating in the blood. This is evident as the platelet count on the lab report. In order to credit this symptom, the reduction of platelets cannot be the result of a side effect of a drug.

Q3-23 My lab reports show that I have a low red blood cell count (RBC) along with a low hemoglobogin (Hgb) and low hematocrit (Hct). Why didn't you credit hemolytic anemia?

A Exhibit E1 requires that the lab report reflect a low RBC, low Hgb, low Hct **and** an increased reticulocyte count. Because you did not have an increased reticulocyte count, you do not meet settlement criteria for hemolytic anemia.

Q3-24 My deficiency letter is asking for the missing reticulocyte count. Isn't it included in the CBC lab report?

A No. A reticulocyte count is not a routine component of the CBC and must be ordered in addition to the CBC.

Q3-25 My physician told me that I have iron deficient anemia. Why haven't you credited hemolytic anemia?

A Iron deficient anemia is a different medical condition than hemolytic anemia.

Q3-26 I sent in lab reports that reflect both leukopenia and lymphopenia. My deficiency letter indicated that both were credited symptoms under hematologic disorder. Why don't these count as two credited symptoms?

A Leukopenia and lymphopenia are two of the four lab tests that can be used to establish the lupus symptom of hematologic disorder. Regardless of the number of tests listed that meet settlement criteria for this disorder, hematologic disorder can only count as one lupus symptom.

Q3-27 What is an Immunologic disorder?

A Exhibit E1 defines this as:

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.

a) **LE cell** is a specific cell found in blood specimens of most lupus patients.

b) **Anti-DNA** refers to anti-double stranded DNA antibodies.

c) **Anti-Sm** refers to Anti-Smith antibody; found in lupus.

d) **False positive serologic test for syphilis known to be positive for at least 6 months**. This test is an older test that is infrequently used but the result must be repeated and remain positive for at least 6 months. Also, the results must be confirmed by Treponema pallidum immobilization or fluorescent treponemal antibody absorption test.

Based on an agreement by the Settling Defendants and Settlement Class Counsel, the Claims Office will also accept an abnormal Anti-SSA test, which measures the Ro antibody, as evidence of the immunologic disorder criteria.

To credit immunologic disorder based on any of these tests, we must have the actual lab report that supports this symptom.

Q3-28 Why didn't you credit my single-strand DNA lab report?

A Exhibit E1 requires the Anti-DNA lab test results be reported as an antibody to native, or double-strand DNA.

Q3-29 My lab report reflects a positive anti-smooth muscle antibody. Why didn't you credit this report under anti-SM?

A Exhibit E1 defines anti-SM as the Anti-Smith antibody. Anti-smooth, anti-striated, and anti-skeletal DO NOT satisfy the requirements of this symptom.

Q3-30 My physician noted that I have a positive finding of antiphospholipid antibodies and that this is a criterion for an immunologic disorder of lupus. Why can't you credit it?

A Antiphospholipid is not one of the lab tests found in Exhibit E1.

Q3-31 Why would my doctor request an ANA lab test?

A An ANA (anti-nuclear antibody) lab test is frequently performed to assist the physician in evaluating a possibility of lupus.

Q3-32 Can anything other than lupus cause an abnormal ANA?

A Yes. Some medications can cause the ANA result to be abnormal. Remember, Exhibit E1 requires that the abnormal ANA occur **in the absence of drugs known to be associated with drug-induced lupus syndrome.**

SECTION 4 COMPENSATION LEVELS

Q4-1 How is compensation level A defined?

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.

Q4-2 What medical records do I need to support my chronic renal involvement?

A You need to send to the Claims Office the laboratory reports reflecting your 24-hour urine specimen, along with all of your medical records supporting your SLE and documenting that your chronic renal involvement is due to your lupus.

Q4-3 My wife had a diagnosis of lupus and is deceased. Her death certificate states lupus as a secondary cause of death. Is this enough for her estate to be paid for compensation level A?

A Compensation level A on the basis of death resulting from systemic lupus erythematosus, (SLE), may be credited if the death certificate reflects SLE or one of the claimant's credited SLE symptoms or complications from SLE as either the primary or secondary cause of death. In addition, the supporting medical records establishing lupus must be contained in the file.

Q4-4 My wife is a deceased claimant. What legal paperwork do I need to submit so that my wife's estate can be paid?

A Along with either a death certificate that reflects SLE as a cause of death or medical records reflecting severe renal involvement that meet the 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.claimsoffice-926.com.

Q4-5 What is the standard used by the Claims Office for determining the age and gender adjusted norm?

A 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.

Q4-6 How is compensation level B defined?

A 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, thrombocytopenia purpura, hemolytic anemia (with hemoglobin of 10 grams or less), severe granulocytopenia (with a total white cell count less than 2000), or mesenteric vasculitis.

Q4-7 My doctor says that I have Central Nervous System (CNS) lupus-- will this meet the compensation level B criteria?

A Possibly, however the neurological conditions that are part of the B level compensation are seizures in the absence of offending drugs or known metabolic derangements and Lupus Psychosis. Your seizures must be related to your SLE and not caused by medications, electrolyte disturbances, or something other than your lupus. In addition, you must also be credited with the corresponding criterion #8, Neurologic disorder. [See also Q3-20]

Q4-8 What is lupus psychosis?

Lupus psychosis is a specific condition that could be a result of your SLE. Lupus psychosis must be documented by your physician and your medical records must support this diagnosis. There is no corresponding lupus symptom for this condition.

Q4-9 What is glomerulonephritis and what medical records do I need to support this diagnosis?

A Glomerulonephritis is inflammation of the glomerulus of the kidney. This condition must be caused by your lupus. Your medical records must reflect an actual diagnosis of glomerulonephritis as well as supporting lab reports reflecting persistent protein in your urine. You must be credited with the corresponding criterion #7 Renal disorder. [See also Q3-17].

Q4-10 What is myocarditis and what medical records do I need to support this diagnosis?

A Myocarditis is inflammation of the muscular walls of the heart. Your medical records must reflect an actual diagnosis of myocarditis. An ultrasound of the heart (echocardiogram) may be performed and may show a pericardial effusion which is fluid in the sac surrounding the heart. You must be credited with the corresponding criterion #6, Serositis based on pericarditis. [See also Q3-14].

Q4-11 What is lupus peumonitis and what medical records do I need to support this diagnosis?

A Pneumonitis is inflammation of the lungs. Your medical records must reflect an actual diagnosis of lupus pneumonitis as well as records that support this diagnosis and treatment of this condition. Sometimes a lung biopsy is required to differentiate pheumonitis from other lung diseases. You must be credited with the corresponding criterion #6, Serositis based on pleuritis. [See also Q3-14].

Q4-12 What is thrombocytopenic purpura and what medical records do I need to support this diagnosis?

A Thrombocytopenic purpura is a small hemorrhage in the skin or mucous membranes which is caused by a decrease in the number of blood platelets. Your medical records must reflect an actual diagnosis of thrombocytopenic purpura and the lab reports supporting the decreased platelet counts. You must be credited with the corresponding criterion #9, Hematologic disorder based on thrombocytopenia. [See also Q3-22d].

Q4-13 What is hemolytic anemia and what medical records do I need to support this diagnosis?

A Hemolytic anemia is caused by the premature destruction of red blood cells. Your medical records must reflect an actual diagnosis of hemolytic anemia with supporting lab reports. You must be credited with the corresponding criterion #9, Hematologic disorder based on Hemolytic anemia. [See also Q3-22a].

Q4-14 What is severe granulocytopenia and what medical records do I need to support this diagnosis?

A Severe granulocytopenia is a total white blood cell count of less than 2000 cells and your lab reports documenting this condition must be submitted to the Claims Office. You must be credited with the corresponding criterion #9, Hematologic disorder based on Leukopenia. [See also Q3-22b].

Q4-15 What is mesenteric vasculitis and what medical records do I need to support this diagnosis?

A Mesenteric vasculitis is inflammation of the blood supply to the small and large intestines. There is no corresponding lupus symptom for mesenteric vasculitis, so the physician who is treating you for this condition must provide documentation that this disorder is related to your lupus.

Q4-16 How is compensation level C defined?

A A diagnosis of lupus, in accordance with the criteria contained in Exhibit E1, that does not involve the findings of compensation level A or B. This is the default compensation level. However, your medical records must reflect regular medical attention including doctor visits and prescription medications in order to qualify for compensation level C. Otherwise, your lupus may fall within the settlement's definition of mild lupus, i.e., "SLE not requiring regular medical attention including doctor visits and regular prescription medications."