

## **Study of Intravenous Infliximab for Sciatica**

### **An Integrated Treatment Program**

**A novel, non-invasive, treatment method designed to quickly reduce the pain and disability of sciatica and reduce lost work time**

#### **1. Background**

Scientific discoveries just in the last 5 years have shown conclusively that our spinal discs produce a substance called tumor necrosis factor alpha (TNF<sub>α</sub>), which is the most powerful proinflammatory substance ever discovered.

We now know that herniated discs do not have to actually mechanically compress a nerve root to cause back pain or sciatica (pain going down the leg). Simply applying TNF<sub>α</sub> to a nerve root in the spine will cause the nerve to become inflamed and produce pain signals. Research has shown that applying a substance that blocks the action of TNF<sub>α</sub> will prevent the nerve from becoming inflamed.

In 1998 the FDA approved the use of infliximab (Remicade), a specific blocker of TNF<sub>α</sub> where we are seeing incredible success rates in patients who had previously never benefited from any therapy.

Because Dr. Atcheson has personally supervised over 2,000 Remicade infusions in his rheumatology practice over the past 3 years, we feel comfortable in offering an evidence-based, integrated treatment program for patients with low back pain and sciatica.

This will be an open-label study of the efficacy of a single infusion of intravenous Remicade in patients with sciatica of up to 12 months in duration. The study will be open to patients with both industrially-related and non-industrial sciatica.

#### **2. Study Program: Option One**

##### **a. Pre-infusion office visit**

Verify eligibility and likely safety of treatment:

    Complete history and physical examination

    Tuberculin skin test applied, if necessary

    Basic patient instruction in the natural history of back pain and

sciatica

    Explanation of Remicade treatment protocol, risks, and potential

benefits

##### **b. Remicade infusion visit (3 – 3 ½ hours)**

1. Medical Assessment:

    Physical exam

where we are seeing incredible success rates in patients who had previously never benefited from any therapy.

Because Dr. Atcheson has personally supervised over 2,000 Remicade infusions in his rheumatology practice over the past 3 years, we feel comfortable in offering an evidence-based, integrated treatment program for patients with low back pain and sciatica.

This will be an open-label study of the efficacy of a single infusion of intravenous Remicade in patients with sciatica of up to 12 months in duration. The study will be open to patients with both industrially-related and non-industrial sciatica.

## **2. Study Program: Option One**

### **a. Pre-infusion office visit**

Verify eligibility and likely safety of treatment:

    Complete history and physical examination

    Tuberculin skin test applied, if necessary

Basic patient instruction in the natural history of back pain and sciatica

Explanation of Remicade treatment protocol, risks, and potential benefits

### **b. Remicade infusion visit (3 – 3 ½ hours)**

1. Medical Assessment:

    Physical exam

    Pain level assessment using 100mm Visual Analog Scale (VAS)

    Pain drawing

2. Remicade infusion:

    The drug is supplied in 100 mg vials and administered at  $\geq$  3 mg/kg body weight, as follows:

3. Post-infusion Assessment

### **c. One week follow-up visit**

History and physical examination, including detailed spine and lower extremity neurological exam

    Pain drawing

    VAS for pain

    Start Phase I of the SpecialtyHealth spine rehabilitation program\*

### **d. Two week follow-up visit**

History and physical examination, including detailed spine and lower extremity neurological exam

    Pain drawing

    VAS for pain

    Continue self-directed spine rehabilitation program

**e. Four week follow-up visit**

- History and physical examination, including detailed spine and lower extremity neurological exam
- Pain drawing
- VAS for pain
- Start Phase II of the SpecialtyHealth spine rehabilitation program\*

**f. Eight week follow-up visit**

- History and physical examination, including detailed spine and lower extremity neurological exam
- Pain drawing
- VAS for pain
- Start Phase III of the SpecialtyHealth spine rehabilitation program\*

**A Summary Report** of the results of the treatment program, including change in pain and whether patient has reached maximal medical improvement for the injury, will be furnished to the claims administrator and to the referring physician. It is not necessary for a workers' compensation patient to formally change treating physicians to enroll in this program. The SpecialtyHealth team can function as consultants, just like those physicians who administer epidural steroids for sciatica and monitor the results of therapy.

\* The SpecialtyHealth spine rehabilitation program is a self-directed exercise program taught by our Clinic personnel. It does not use any formal physical therapy visits.

**3. Alternative Program: Option Two**

For those patients who do not wish to participate in the study, but whose referring physicians **a. Option One**

**Visit**

1. Study Eligibility
2. Remicade infusion
  - Medical assessment
  - Remicade (J1745)
  - First hour infusion
  - 2<sup>nd</sup> and 3<sup>rd</sup> hours
3. One week follow up
4. Two week follow up
5. Four week follow up
6. Eight week follow up

**b. Option Two**

**Visit**

1. Study Eligibility
2. Remicade infusion
  - Medical assessment
  - Remicade (J1745)

**a. Option One**

**Visit**

1. Study Eligibility
2. Remicade infusion
  - Medical assessment
  - Remicade (J1745)
  - First hour infusion
  - 2<sup>nd</sup> and 3<sup>rd</sup> hours
3. One week follow up
4. Two week follow up
5. Four week follow up
6. Eight week follow up

**b. Option Two**

**Visit**

1. Study Eligibility
2. Remicade infusion
  - Medical assessment
  - Remicade (J1745)
  - First hour infusion
  - 2<sup>nd</sup> and 3<sup>rd</sup> hours
3. Two week follow up

**5. Requirements for Treatment**

- a. Competent adult
- b. True sciatica (radiation of pain from the back to below the knee in a radicular or dermatomal pattern) in one or both legs
- c. MRI of the lumbar spine performed prior to treatment
- d. Negative tuberculin skin test, or known prior completed treatment for TB, or prior BCG vaccination with inactive chest X-ray
- e. No evidence of congestive heart failure or active infection

Prior epidural steroid injections or lumbar discectomy will not disqualify a potential participant