MS As A Disease, Copaxone® As a Treatment and MS Patient Care

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THE EARLIEST CASES

- Described for many centuries
- First Case – Lidwina Van Schiedam
  Noted in 1421
- Became more well documented in the 1800s
- Well described by Charcot in the late 1800s – Correlated clinical science and pathology – opened the door for others to build on his work.
Early treatment centered on the current therapies that apply to any illness

Early etiologic theories:
- Worry and overwork
- Spirochete
- Toxins – heavy metal poisons
- Infections
EARLY INTERVENTION

- Manage relapse
- Symptom Management
- Physical therapy for rehabilitation
Origin of MS

- Geographic distribution suggests environmental factor
- Viral hypothesis
- Native Americans, Eskimos, Lapps and Hungarian gypsies genetically protected.
Demographics of MS

- Age of onset 15 to 45 years
- Gender 70% women
- Geography incidence increases with distance from equator
- Incidence 8,500 to 10,000 new cases per year
- Prevalence 350,000 in U.S.

Genetic Prevalence of MS

- 10 X increase for MS if direct relative affected.
- Higher prevalence in identical twins.
- Variability in severity of disease in twins and affected relatives.
Course of disease in MS

1. Relapsing-remitting
2. Primary-progressive
3. Secondary-progressive
4. Progressive-relapsing

Percent of patients presenting with relapsing-remitting MS

- 85% Relapsing-remitting
- 15% Other

- 50% of patients require walking aids within 15 years of diagnosis

Direct costs of MS

- Care provided professionally or by family
- Home alterations, special equipment, transportation, disease-specific medical costs, etc.

- Total annual cost
  - $9.7 billion for health care system in 1994 dollars
  - average $35,000 per patient per year
    - $50,000 for primary-progressive
    - $30,500 for relapsing-remitting

Indirect costs of MS—lost days

- Patients still working lose no more days than peers
- Restricted activity
  - 23% are restricted 1-7 days/2 weeks
  - 16% are restricted 8-14 days/2 weeks
- Confined to bed
  - 27% confined to bed ≥ 1 day/2 weeks
  - 10% totally confined to bed

Clinical Presentation of MS

- Primary Symptoms
  - Visual complaints, gait problems, pain, spasticity, weakness, speech difficulty, bladder/bowel dysfunction

- Secondary Symptoms
  - UTIs, urinary calculi, muscle contractures, URI, poor nutrition

- Tertiary Symptoms
  - financial, social, emotional, vocational problems
Diagnosis:

- **Neurological examination**
  - (dissemination in time and space)

- **Magnetic Resonance Imaging**

- **Cerebro-spinal fluid**
  - (Oligoclonal bands, intrathecal IgG)

- **Evoked potential VEP**
Principles of management

- Treat relapses
- Manage symptoms
- Modify/reduce relapses
- Delay progression to disability
- Facilitate an acceptable quality of life
Principles of management

- Manage symptoms
  - fatigue
  - spasticity
  - pain
  - bowel, bladder
  - memory loss and affective disorders
  - swallowing problems

- Psychological and emotional support
  - tremors
  - visual changes
  - sexual problems
  - speech disorders
  - balance and mobility dysfunction
Treatments

1/ Acute exacerbation: i.v. steroids

2/ Long term immunomodulation:
   a. interferons
   b. GA - selective immunomodulation

3/ Symptomatic relief

4/ Management of treatments’ side effects
MS Immunotherapy

Currently four immunomodulatory drugs are available for use in the treatment of Multiple Sclerosis:

- **Avonex™**: Interferon β 1a
- **Betaseron®**: Interferon β 1b
- **Copaxone®**: Glatiramer Acetate
- **Rebif®**: Interferon β 1a
Factors that influence treatment decisions

- Stage of disease and amount of recent disease activity
- Magnetic resonance imaging (MRI) lesion burden
- Safety and tolerability profiles of immunomodulating agents
- Patient preferences, expectations, capabilities, and lifestyle issues
Adherence to Therapeutic Regimens

- Considerable barrier to health care regimens
  - 30-70% nonadherence, average 50%
- Adherence as opposed to compliance
  - incongruent to nurse-patient relationship
  - compliance “the extent to which a person’s behavior coincides with medical or health advice”
  - adherence “active, voluntary and collaborative involvement of the patient in a mutually acceptable course of behavior that leads to therapeutic outcomes”
Barriers to Adherence in MS

- Communication problems
- Knowledge deficits
- Physical impairments
- Social and cultural variables
- Financial concerns
- Emotional distress
- Psychiatric disorders
- Cognitive deficits
Lifestyle issues

- Maintain balance between side effects and efficacy (risk/benefit ratio)
- Factor individual patient circumstances into equation (e.g., employment, schedule, family responsibilities, capabilities, physical assessment)
Indications and Usage

- Copaxone is indicated for reduction of the frequency of relapses in patients with RRMS
Copaxone® Safety Data

- Placebo Controlled Trials in R - R patients
  - (269 GA : 271 Placebo)

- Open label trials 3,736 patients

- Post marketing safety data (active surveillance)
  - (> 40,000 patients)
COPAXONE®

- Five studies, 181 investigators, 706 patients all point to one common conclusion- COPAXONE® effectively reduces relapse rates, has favorable effects on both disability, and virtually all MRI parameters.
- It has been shown to have a sustained effect for over a 8 year period
Customer Support Resources

- Shared Solutions – Call Center
  - Enrollment Process
  - Home Health
  - Benefits Investigation
  - Autoject
  - Patient Support / Education
    - Literature / Materials
    - Adherence & Compliance

- MS Watch
- Patient Assistance
Who We Serve

External:
- Patients
- Caregivers
- Physicians

Internal:
- Sales Associates
- Marketing
- Medical
Current State

A. Transition Completed 9/30/02

B. Shared Solutions® Members: 84,315
   On COPAXONE®: 54,063

A. Average Enrollments per Month: 1,835

B. Staffing
   24 Nurses
   19 CSRs

C. Siebel CRM System

D. Avaya Computer Integrated Telephony

E. Coverage 7:00am – 10:00pm CST M-F
Call Center Activity

- Inbound Call Volume 2002 – 18,500/month
  - 4th Quarter – 10,500/month

- Outbound Compliance Call Volume approx. 9,000/month
  - Compliance Call Schedule
Compliance/Adherence Opportunities

- Script to First Injection Elapsed Time 21 days
- Decreased 90 Day Drop Rate 37%
- Decreased 360+ Day Drop Rate 37%
Shared Opportunity

- New Enrollees
- Increased Level of Support for Physician Offices
- Expedited Time to Product
- Increased Compliance & Adherence
- Optimize Business Results

Sales Force + Shared Solutions = Win

Win, Patients, TNS
CSR

- Triage calls
- Return voicemail
- Enroll callers in SS
- Obtain orders from physicians
- Provide information
Nurse

- Educate
- Support
- Set realistic expectations
- File reports
- Outbound calls to patients
Patient Assistance Programs

- **NORD**
  Program for uninsured/underinsured patients to obtain COPAXONE®

- **PSI**
  Assistance with co-payments/co-insurances
NORD has served MS Patients since...

- **1994 to 1996** – COPAXONE® Early Access Program

- **1996 to present** - COPAXONE® Patient Assistance Program

- **6,000+** referrals to NORD since 1996
Who is eligible for COPAXONE® Assistance?

- Individuals diagnosed with RR-MS
- The uninsured
- Health insurance does not include Rx coverage
- Income is too high for Medicaid but too low to pay out-of-pocket for COPAXONE®
COPAXONE® Demographics...

- Out of 1,800+ active patients in the COPAXONE® Patient Assistance Program:
  - 74% Female
  - 26% Male
COPAXONE® - NORD ACTIVITY

Inquiries
New Pts
Patient Assistance Programs

- **PSI**
  Assistance with co-payments/co-insurances
GAPS in Most Corporate PAP’S

- Can not pay health insurance premiums
- Can not pay co-payment and deductible
PSI Provides These Services

- **Premium Assistance Program**
  - Cobra Payments
  - High-risk Payments
  - Open-enrollment Payments
  - Full Assistance or Share-of-Cost

- **Co-payment Assistance Program**
  - Full Assistance or Share-of-Cost
COST SHARING
based on PSI criteria

• **General Living Expenses**
  
  To Include:
  
  - Rent/Mortgage
  - Food
  - Utilities
  - Clothing, etc.

• **Number of Dependents**

• **State where family resides**
GROWTH OF PSI CASELOAD
(ALL MS THERAPIES)
COPAXONE Assisted Patients Through PSI

- Number of patients served: 600
- Number of patients by year end: 1,000