Implementing Evidenced-Based Treatment Regimens, New Models of Care, and Patient Management Strategies for Multiple Sclerosis

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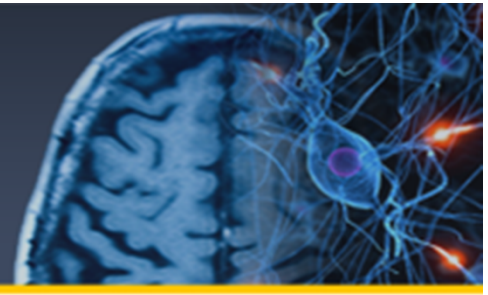
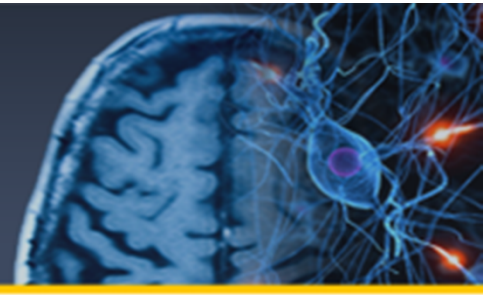
Agenda



6:20 – 6:45 am	**Optimizing Therapeutic Decision-Making for MS** *Fred D. Lublin, MD, FAAN, FANA*
6:45 – 7:05 am	**Welcome to the Neighborhood: How New Care Models Can Improve Outcomes for Patients with MS** *Bruce Sherman, MD, FCCP, FACOEM*
7:05 – 7:30 am	**Implementing a Comprehensive MS Care Model: From Benefit Design to Specialty Pharmacy Management Services** *Jeffrey D. Dunn, PharmD, MBA*
7:30 – 7:45 am	**Faculty Discussion/Question and Answer Session**

Educational Objectives



After completing this activity, the participant should be better able to:

- Review current and emerging clinical data to enhance therapeutic decision-making and optimize outcomes for MS treatments
- Implement the necessary collaborations, processes, and systems that will drive successful MS treatment in a complicated new accountable care ecosystem
- Evaluate innovative specialty pharmacy benefit models and specialty management services for MS
- Provide accurate and appropriate counsel as part of the managed care treatment team

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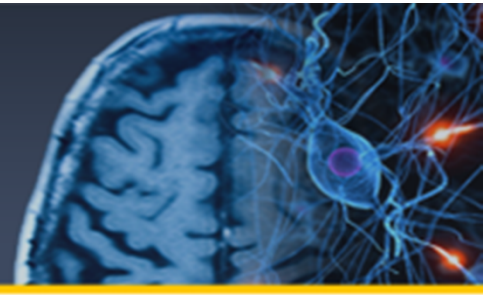
Optimizing Therapeutic Decision-Making for MS

Fred D. Lublin, MD, FAAN, FANA
Saunders Family Professor of Neurology
Director, The Corinne Goldsmith Dickinson Center for Multiple Sclerosis
Icahn School of Medicine at Mount Sinai

Faculty Disclosure



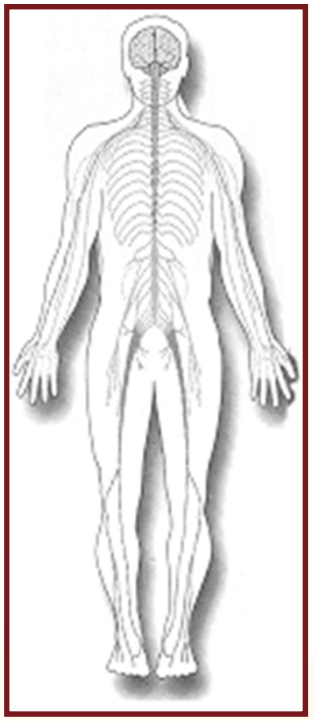
- The ***faculty*** reported the following financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interests related to the content of this CME activity:

  Fred D. Lublin, MD, FAAN, FANA

  - *Consulting Fees:* Bayer HealthCare Pharmaceuticals, Biogen Idec, EMD Serono, Inc., Novartis Pharmaceuticals Corporation, Teva Neuroscience, Actelion, Sanofi-Aventis, Acorda, Questcor, Roche, Genentech, Celgene Corporation, Johnson & Johnson, Revalesio, Coronado Bioscience, Genzyme, MedImmune, Bristol-Myers Squibb, Xenoport, Receptos, Forward Pharma, to-BBB technologies
  - *Research Funding*: Acorda Therapeutics, Inc., Biogen Idec, Novartis Pharmaceuticals Corporation, Teva Neuroscience, Inc., Genzyme, Sanofi-Aventis, Celgene Corporation, Transparency Life Sciences, National Institute of Health, National Multiple Sclerosis Society
  - *Speaker (non-promotional):* Genzyme
  - *Financial Interest:* Cognition Pharmaceuticals, Inc.

Epidemiology

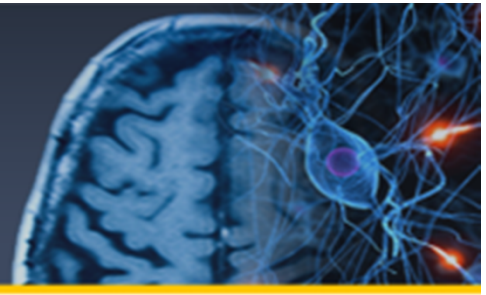
- Most common chronic disease affecting the CNS in young adults
- ~400,000 cases in the United States
- The chances of developing MS are 1:750 in the general population
- >2.5 million cases worldwide
- Highest incidence in Caucasians
- Higher incidence in women (~ 3:1)
- Roughly 75% of cases present between 20 years to 50 years of age



CNS = central nervous system.

National MS Society. Who gets MS? http://www.nationalmssociety.org. Accessed July 22, 2013. Compston A, et al. *Lancet*. 2002;359(9313):1221-1231. Frohman EM. *Med Clin North Am*. 2003;87(4):867-897.

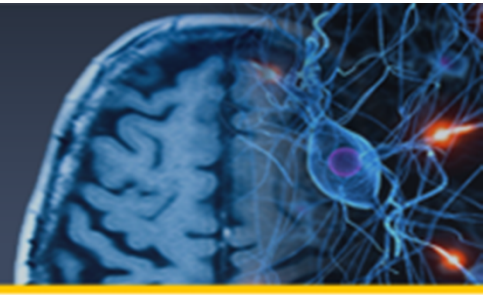
Early/Subclinical Disease Courses

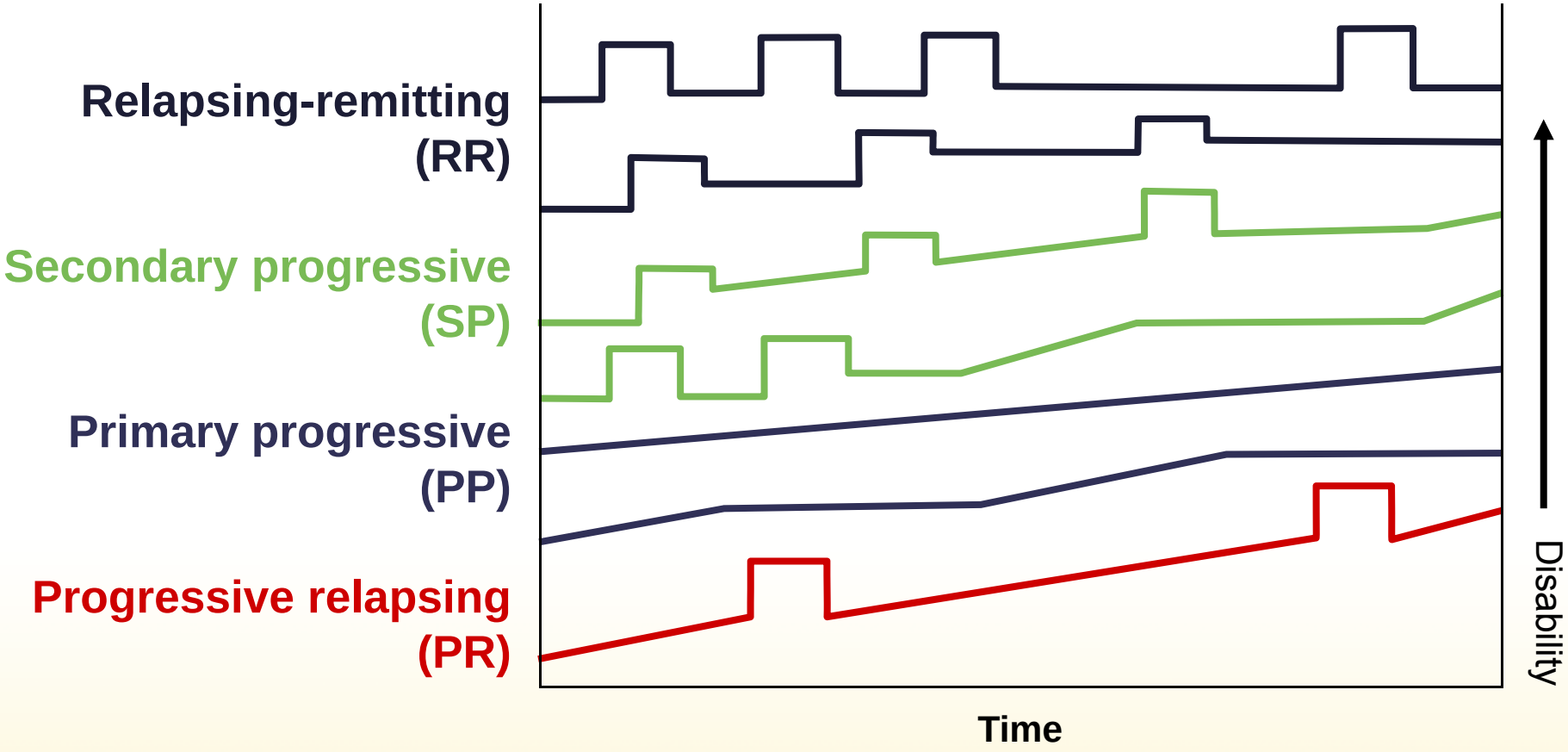


- **Clinically Isolated Syndrome (CIS)**
  First attack of inflammatory demyelinating disease consistent with MS

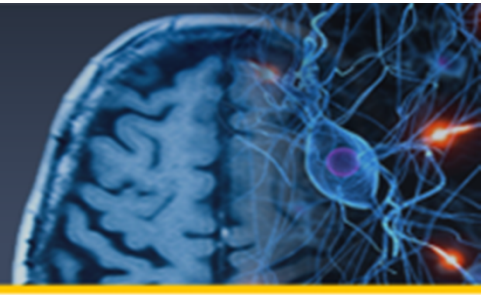
- **Radiologically Isolated Syndrome (RIS)**
  MRI findings consistent with MS absent any clinical episodes

Clinical Patterns of MS





The Clinical Course of MS is Regularly Evaluated and Redefined



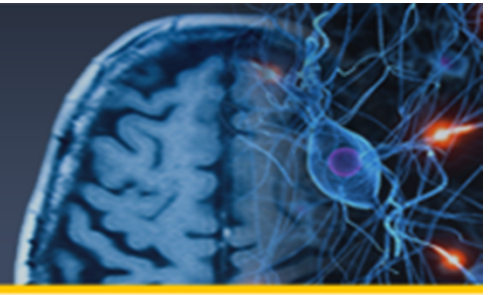
Neurology®

Defining the clinical course of multiple sclerosis: The 2013 revisions

Fred D. Lublin, Stephen C. Reingold, Jeffrey A. Cohen, et al.

Neurology 2014;83;278-286 Published Online before print May 28, 2014
DOI 10.1212/WNL.0000000000000560

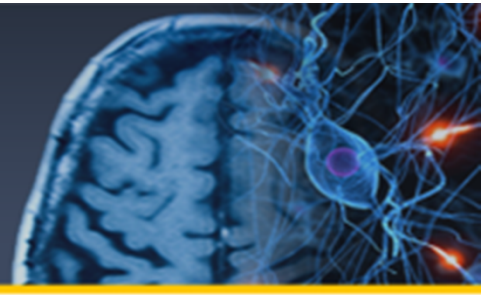
Major Outcomes in MS



- Relapse Rate
  - Time to first relapse
  - ARR
  - Pre- vs post-treatment relapse rate
  - Relapses requiring steroid therapy
  - Relapses resulting in hospitalization
  - The natural history of untreated RRMS is towards a reduction in relapse rate over time as disability accumulates
- Disability
  - Traditionally measured by EDSS
    - Time to change on EDSS
    - Percent patient reaching EDSS milestones
    - *Weaknesses include*: scale is nonlinear, focuses on gait, poor inter/intrarater reliability
  - MSFC
    - Measures gait by timed 25-foot walk, cognition by PASAT, and underlying event function by the 9-hole peg test
- MRI Measures of Disease
  - Gd+ lesions (decrease in a fashion similar to relapses)
  - T2 lesions (number, size, volume)
  - Measures of tissue loss: atrophy, black holes, thinning of the corpus callosum, spinal cord atrophy
  - Is an enhancing lesion on the MRI correlate to clinical relapse?

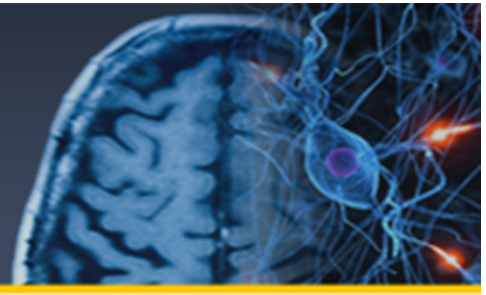
ARR = annualized relapse rate; RRMS = relapsing-remitting multiple sclerosis; EDSS = extended disability status scale;
MSFC = multiple sclerosis functional composite; PASAT = Paced Auditory Serial Addition Test

Who to Treat



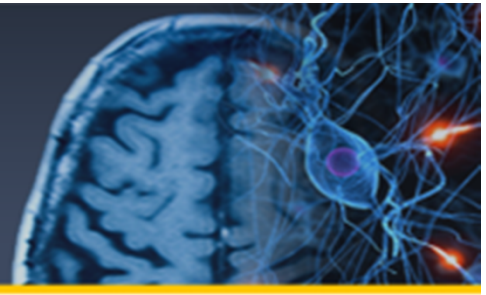
- MS
  - **RR, SP**, PP, **PR**
- CIS
  - MRI
- RIS
  - ???

When to Treat



- First activity
- Subsequent activity
- Wait
- What about benign MS?

When to Treat



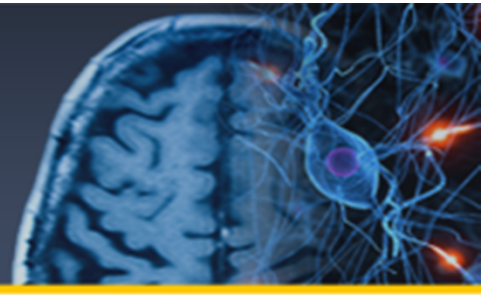
Past thinking

Wait to treat until clinical deterioration

Present thinking

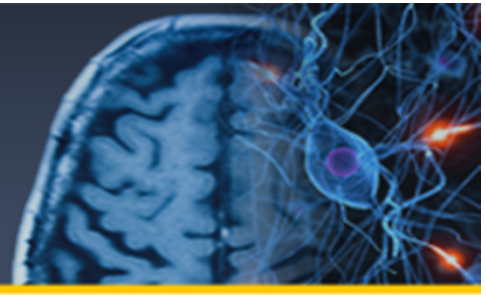
Treat early

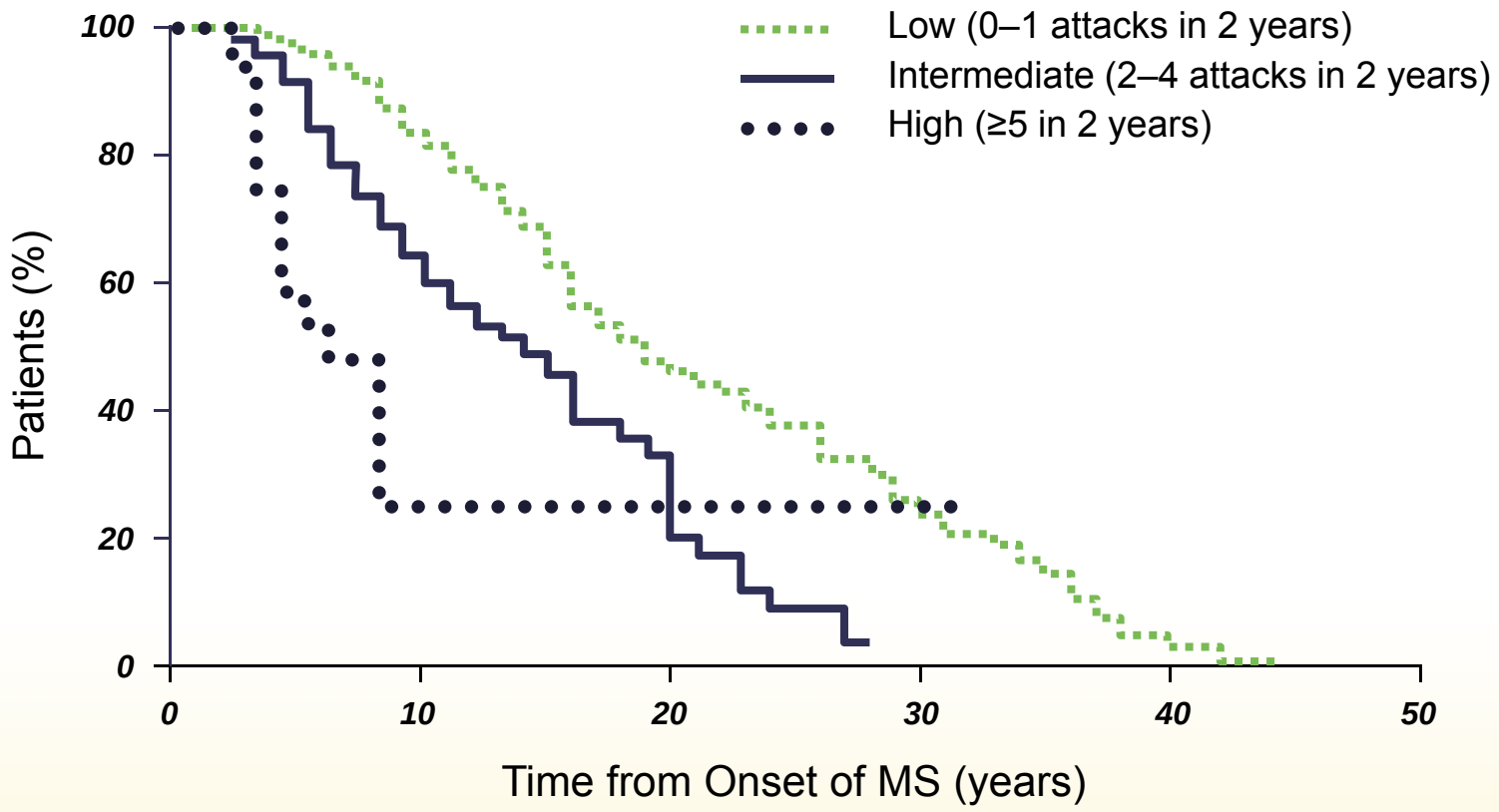
Importance of Early Treatment



- MS may be active in the absence of clinical symptoms
- Lesions may occur early and may be associated with irreversible damage
- Evidence suggests that degenerative changes can occur in normal-appearing white matter
- Early treatment with disease-modifying therapies (DMTs) may help slow the accumulation of damage

Early Relapses Affect Long-Term Disability

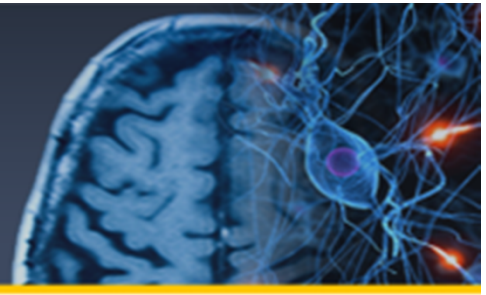




Actuarial analysis of disability: Percentage of patients not having reached EDSS 6: Difference between groups is significant (P<.0001)

Tintoré M. *J Neurol*. 2008;255(suppl 1):37-43. Weinshenker BG, et al. *Brain*. 1989;112(Pt 6):1419-1428.

Available Treatment Options: Disease-Modifying Therapies (DMTs)



GA

- Given by SQ injection at a dose of 20 mg daily or 40 mg 3x weekly

Natalizumab

- Given by IV infusion at a dose of 300 mg every 4 weeks

INF b-1a

- Given by SQ injection at a dose of 22 to 44 mcg 3 times weekly

INF b-1a

- Given by IM injection at a dose of 30 mcg weekly or SC 125 mg biweekly

INF b-1b

- Given by SQ injection at a dose of 250 mcg every other day

Fingolimod

- Given by PO pill at a dose of 0.5 mg daily

Teriflunomide

- Given by PO pill at a dose of 7 mg or 14 mg daily

Dimethyl fumarate (BG-12)

- Given by PO pill at a dose of 240 mg twice daily

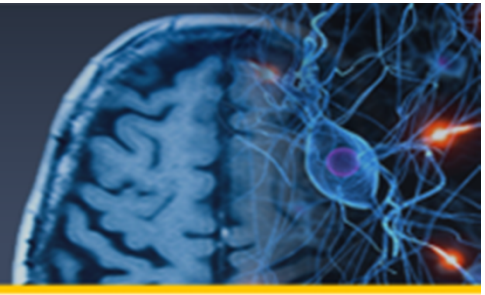
Mitoxantrone

- Given by IV infusion at a dose of 12 mg/m^2 every 3 months

GA = glatiramer acetate; IV = intravenous; PO = by mouth.

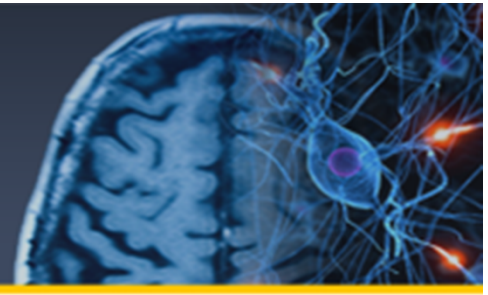
Medications for Modifying the Disease Course. http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/index.aspx. Accessed October 7, 2013.

Clinical Trials of DMTs in CIS Highlight the Importance of Early Treatment



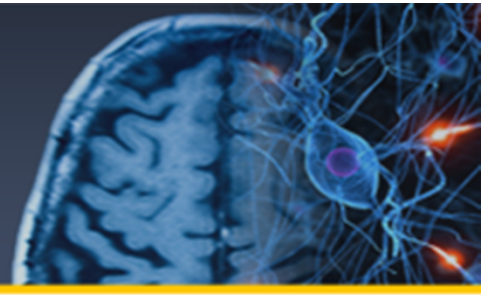
Trial	Agent	Key Outcomes
CHAMPS	INF-b1a	Reduced rate of conversion to CDMS, reduction in volume of brain lesions, fewer new or enlarging lesions
ETOMS	INF-b1a	Reduced rate of conversion to CDMS, delayed time to the occurrence of a second exacerbation
BENEFIT	INF-b1b	Reduced rate of conversion to CDMS, less disease dissemination/activity at onset
PreCISe	GA	Reduced rate of conversion to CDMS, prolonged time to convert to clinically definite disease
REFLEX	INF-b1a	Reduced rate of conversion to CDMS, lower probability of a second lesion on MRI
TOPIC	Teriflunomide	Reduced rate of conversion to CDMS

Hierarchy of DMT Considerations



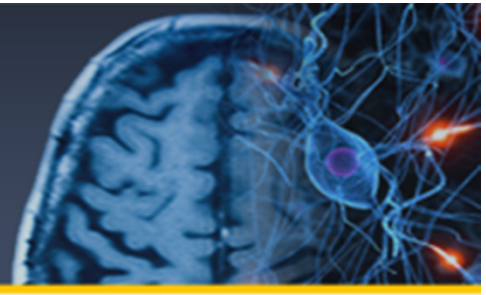
- EFFICACY
- Safety
  - Side Effects
  - Cost/Hassle Factor

Treatment Selection - Clinical



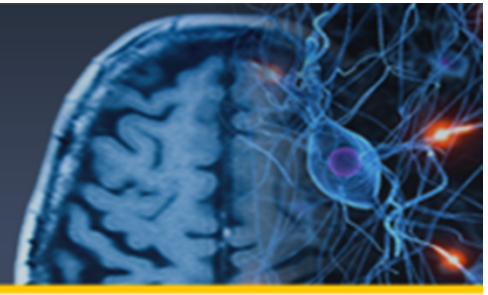
- Natural History vs Unnatural History
- Observational studies
- How to compare – statistical inferences
- Who knows where the biases are?
  - Bias beats statistics

Treatment Selection - Clinical



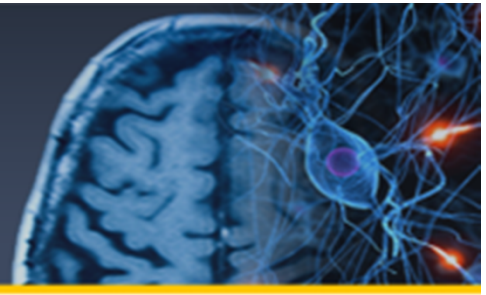
- Comparative studies: head to head: Best
- Tracking Arms: may be underpowered
- Inference: inaccurate but common
- Options: becoming more common

Treatment Selection - MRI



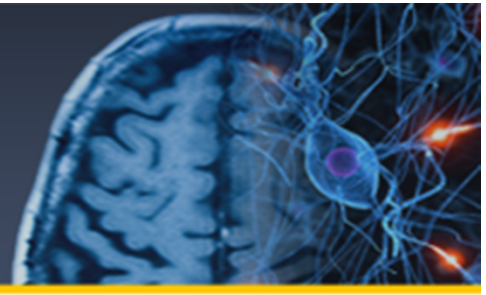
- **Lesion load**
- **Activity**
- **Value as indicator of therapeutic response**

Treatment Selection - Biomarkers



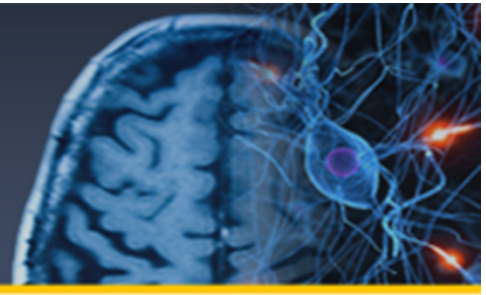
- **Myelin antibodies**
- **Immune markers**
- **Genetics/genomics**
- **Neutralizing antibodies**
- **JC virus exposure**

Treatment Selection - Mechanism of Action



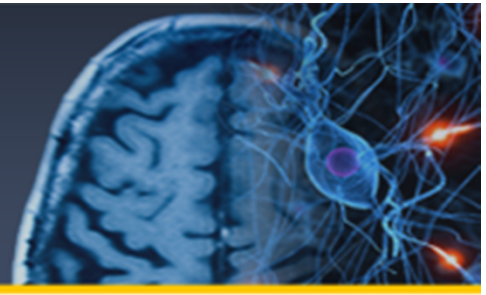
- **Does MOA Matter?**
  - **sometimes**
- **Why?**
  - **Other medical issues**
  - **Prior therapies**
  - **Pregnancy**
- **When**
  - **Future consequences**
  - **Sequencing of therapy**

Treatment Selection - Collaboration with the Patient



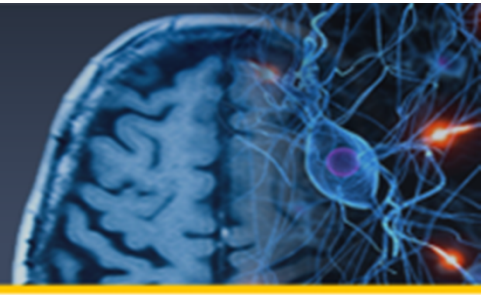
- **Long Discussion**
  - **Getting longer**
- **Partnering- what to discuss**
  - **Efficacy**
  - **Safety**
  - **Convenience**
- **Follow up**
  - **Medical monitoring**
  - **Adherence**

Therapeutic Choices



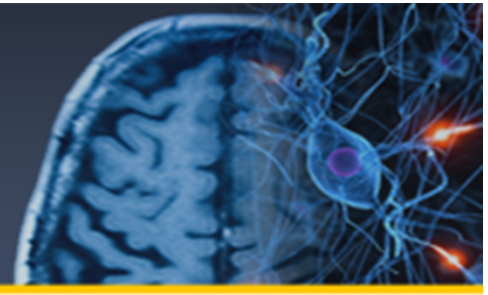
- Escalation
- Induction
- Nothing?

Comparative Efficacy



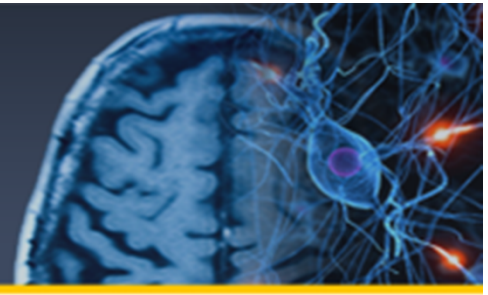
- High dose/frequency v low dose/frequency IFN
- High dose/frequency IFN v GA
- Low dose/frequency IFN v GA
- Low dose/frequency IFN v fingolimod
- High dose/frequency IFN v teriflunomide

Limitations of Treatment



- DMTs are only partially effective
  - Limited data on long-term disability with 2-year trials
- Some DMTs are injectables
  - Self-injections, most SQ
- Safety/side effect monitoring profile of INFs and others

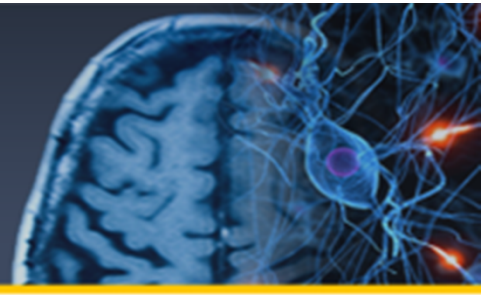
Duration of Treatment



"Therapy is to be continued indefinitely, except for the following circumstances: there is clear lack of benefit; there are intolerable side effects; better therapy becomes available."

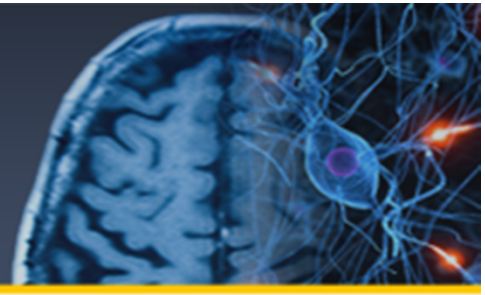
National MS Society. Disease management consensus statement. http://www.nationalmssociety.org/about-multiple-sclerosis/treatments/download.aspx?id=8. Accessed September 24, 2013.

What We Don’t Know



- Long-term efficacy data
- Good comparative efficacy data
- How to define inadequate response
- How to switch therapies

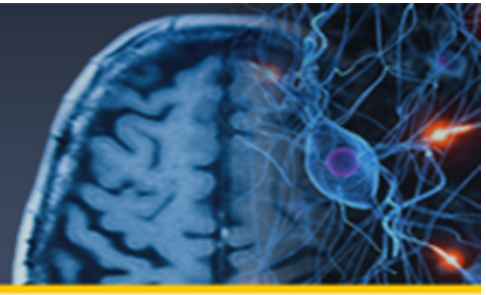
Treatment Optimization: Availability of Multiple Therapeutic Options



- "All of these FDA approved agents should be included in formularies and covered by third-party payers so that physicians and patients can determine the most appropriate agent on an individual basis; failure to do so is unethical and discriminatory."
- "Patients' access to medication should not be limited by the frequency of relapses, age or level of disability."
- "Treatment is not to be stopped while insurers evaluate for continuing coverage of treatment, as this would put patients at increased risk for recurrent disease activity."

National MS Society. Disease management consensus statement. http://www.nationalmssociety.org/about-multiple-sclerosis/treatments/download.aspx?id=8. Accessed September 24, 2013.

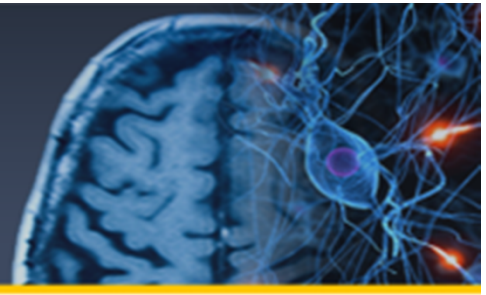
Treatment Optimization: Potential Criteria for Defining a Suboptimal Response



Relapses

- Number of relapses (ARR?)
- Severity of relapses (EDSS)
  - Is there significant loss of function?
  - Was it treated with steroids?
  - Did it require hospitalization?
  - Was there a requirement for rehabilitation
- Location of relapses (brain vs spinal cord)
- Systems involved (motor vs sensory)
- Complete vs partial recovery from relapses

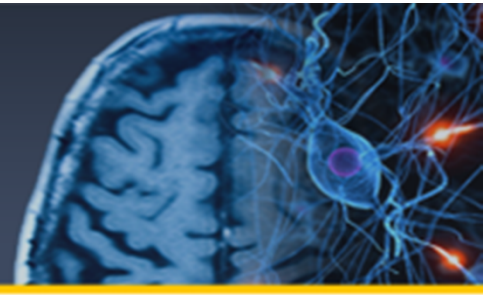
Treatment Optimization: Potential Criteria for Defining a Suboptimal Response (cont)



Disability

- Don’t use change in EDSS during attack, in isolation, as a determinant of treatment failure
- Annual increase in EDSS of ≥1 in patients with a previous score of 3.0 to 5.5, or ≥0.5 with a previous score of ≥6.0, should raise concern
- Measurement of change in very low EDSS ranges (3.0) is too variable to be used in isolation to define treatment failure

Treatment Optimization: Potential Criteria for Defining a Suboptimal Response (cont)

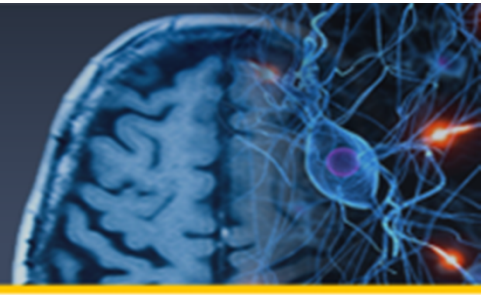


Radiologic/MRI signs

- New or recurrent brain stem or spinal cord lesions
- Increasing lesion number on MRI
  - 3 enhancing lesions in 1 year
  - >3 new T2 lesions in 1 year
  - ≥2 new T2 lesions on each repeated scan performed at ≤3 month intervals
- Increasing lesion size on MRI, most notably
  - In more than 2 types of lesions
  - In presence of EDSS worsening independent of attacks

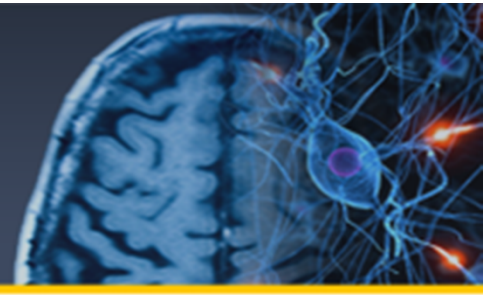
Cohen BA, et al. *Neurology*. 2004;63(12 suppl 6):S33-S40. Coyle PK. *J Neurol.* 2008;255(suppl 1):44-50. Freedman MS, et al. *Can J Neurol Sci*. 2004;31(2):157-168. National MS Society. 2004. Available at: http://www.nationalmssociety.org/download.aspx?id=129. Accessed November 28, 2012.

What's Coming: Emerging and Investigational Agents



Agent	Mechanism	Administration	Target Patient Population; Development Status	Key RCTs
ocrelizumab	anti-CD20 monoclonal antibody	IV	PPMS, RRMS; phase 3	ORATORIO, OPERA I & II
alemtuzumab	anti-CD52 monoclonal antibody	IV	RRMS; phase 3	CARE-MS I & II
daclizumab high-yield process (HYP)	anti-CD25 monoclonal antibody	IV	RRMS; phase 3	DECIDE
Tcelna®	T-cell immunotherapy (vaccine)	IV	RRMS; phase 2b/3	Abili-T
laquinimod	immunomodulator	oral	RRMS; phase 3	BRAVO
masitinib	protein kinase inhibitor	oral	PPMS; phase 2b/3 (Spain)	*Trial currently recruiting*

What's Coming: Disease Assessment



- Assessment of activity
  - Clinical
  - MRI
- Assessment of progression

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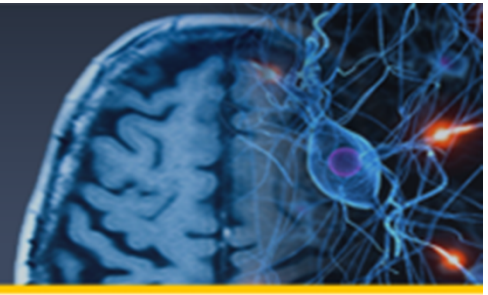
This activity is supported by educational grants from Genzyme, a Sanofi company, Novartis Pharmaceuticals Corporation, and Teva Pharmaceutical Industries.

Welcome to the Neighborhood: How New Care Models Can Improve Outcomes for Patients with MS

Bruce Sherman, MD, FCCP, FACOEM
Consulting Corporate Medical Director, Wal-Mart Stores, Inc.
Medical Director, Employers Health Coalition

Faculty Disclosure



- The ***faculty*** reported the following financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interests related to the content of this CME activity:

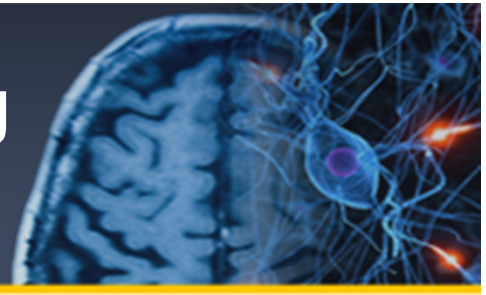
  Bruce Sherman, MD, FCCP, FACOEM

  – *Consulting Fees:* Humana, Inc., Merck & Co., Inc.,

  – *Fees for Non-CME/CE Services:* Abbvie, Eisai Pharmaceuticals, Merck & Co., Inc., Pfizer Inc.

  – *Research Grant:* Pfizer, Inc.

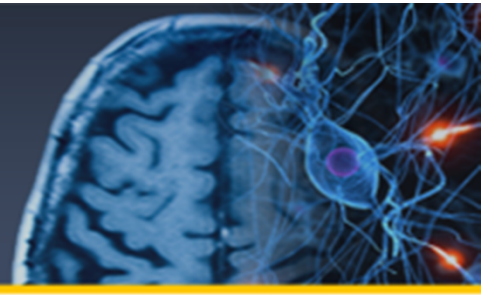
Healthcare Reform Legislation is Driving a Shift from Volume to Value



- Payment/delivery paradigm emphasis is on rewarding value instead of volume
  - Value-based purchasing, shared savings, gain-sharing, bundled payments, capitation, etc
- Incentives such as the CMS 5-Star Rating System are being implemented to coordinate care among/across providers
  - Beginning in January 2012, plans with ≥4 stars receive bonuses along with higher rebates and plans with ≤3 stars will be flagged as “low-quality” on the Medicare website
- New structures are promoting actual and virtual integration
  - ACOs, medical homes, home-based chronic care management, community health teams, healthcare innovation zones

CMS = Centers for Medicare and Medicaid Services; ACOs = accountable care organizations.

The Evolving Health Care Environment in the Post-Reform Era



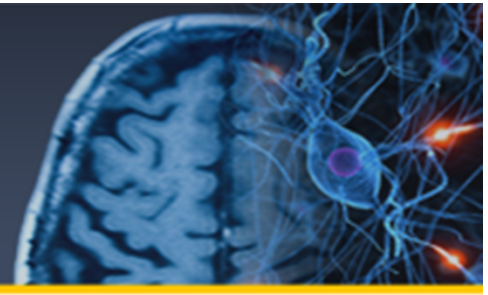
Present

- Perverse incentives—volume over value
- Unsustainable healthcare cost trajectory
- Medicare and Medicaid will cut payment rates
- Will reach a point where we can no longer cost-shift to commercial payers to make up for declining government payment levels
- Efficiency gains will not be enough for success

Future

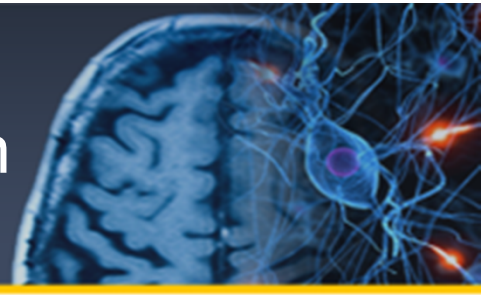
- Consequences of care outcomes will be shared between payers and providers
- Primary care will be pivotal in managing health and utilization
- Proactively managing the health of individuals will be rewarded
- Proactively managing the health of our communities will be rewarded
- If we can perform better than others, we have more to gain financially in a capitation environment
- In Medicaid and exchanges, there will be even more emphasis on cost and generics

New Models Have Emerged Based on These Consistent Themes in Health Care Quality



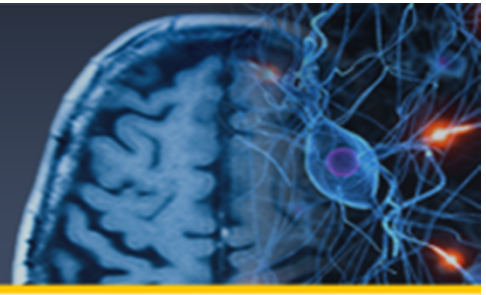
- Organizational structures that support proactive, patient-centered care, quality improvement, and clinical integration
  - Patient-centered medical home (PCMH)
  - Accountable Care Organization (ACO)
- Payment mechanisms focused on “fee-for-value” rather than “fee-for-volume”
  - Quality incentives for improved processes and outcomes
  - Likely to evolve in steps: FFS – Per Case/“at-risk” quality payments – Bundled – Capitation

The PCMH Model and ACO models are Aligned with the Shifting Paradigm in Health Care



- ***PCMH*** is characterized by:
  - A *personal physician* who coordinates all care for patients and leads the team.
  - *Physician-directed medical practice* – a coordinated team of professionals who work together to care for patients.
  - *Whole person orientation* – this approach is key to providing comprehensive care.
  - *Coordinated care* that incorporates all components of the complex health care system.
  - *Quality and safety* – medical practices voluntarily engage in quality improvement activities to ensure patient safety is always being met.
  - *Enhanced access to care* – such as through open-access scheduling and communication mechanisms.
  - *Payment* – a system of reimbursement reflective of the true value of coordinated care and innovation.
- ***ACOs*** are directly linked to health care reform law:
  - Legal entity through which the Affordable Care Act's (ACA) Shared Savings Program is implemented
  - ACO member personnel work together to coordinate and manage care
  - Mechanism for shared governance that provides ACO participants with proportionate control over decision-making process

The PCMH Model Capitalizes on the Benefits of Primary Care

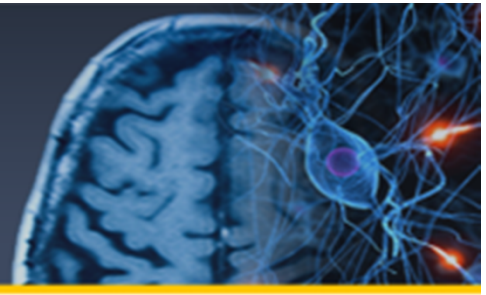


- For each 1 percent increase in primary care physicians, average-sized metropolitan areas experienced a decrease of 503 hospital admissions 2,968 emergency room visits 512 surgeries.[1]

- Hospitalization rates and expenditures for ambulatory care-sensitive conditions are higher in areas where there are fewer primary care physicians and where access to primary care is limited.[2]

1. Kravet SJ, et al. *Amer J Med.* 2008;121.2:142-148.
2. Bodenheimer T, et al. *Ann Intern Med.* 2005;143.01:23-31.

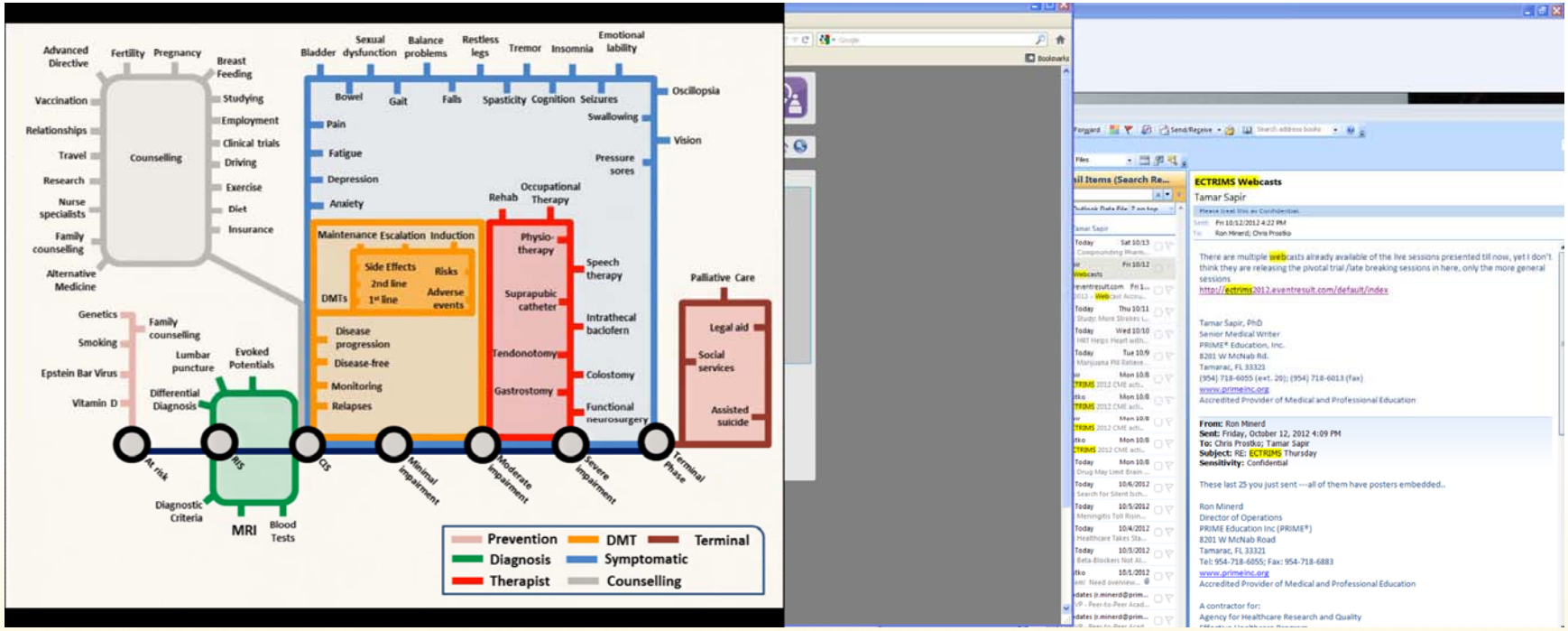
MS is Among the Chronic Conditions Most Often Treated in Primary Care



Condition	Treated by PCP
Asthma	80%
Congestive Heart Failure	88%
Coronary Heart Disease	88%
Depression/Anxiety	81%
Diabetes	88%
Hypertension	88%
Multiple Sclerosis	**77%**
Parkinson's	90%

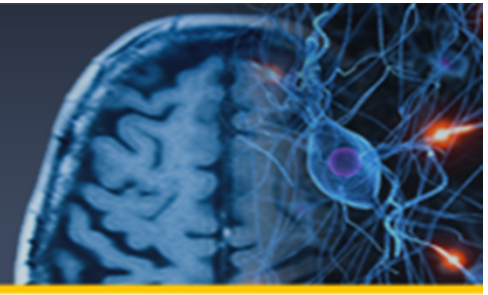
CDC. National Health Interview Survey. Available at: http://www.cdc.gov/nchs/nhis.htm.

MS is a Complex Disease Requiring Care Coordinated Among Numerous HCPs



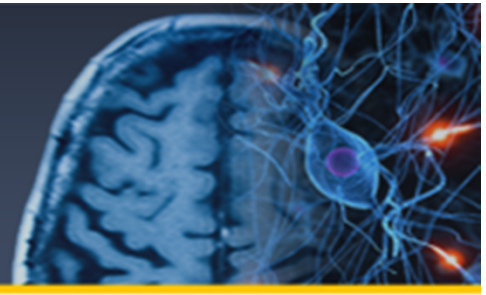
Giovanonni G, et al. Presented at: 28th Congress of ECTRIMS; October 9-13, 2012; Lyon, France. Abstract 173.

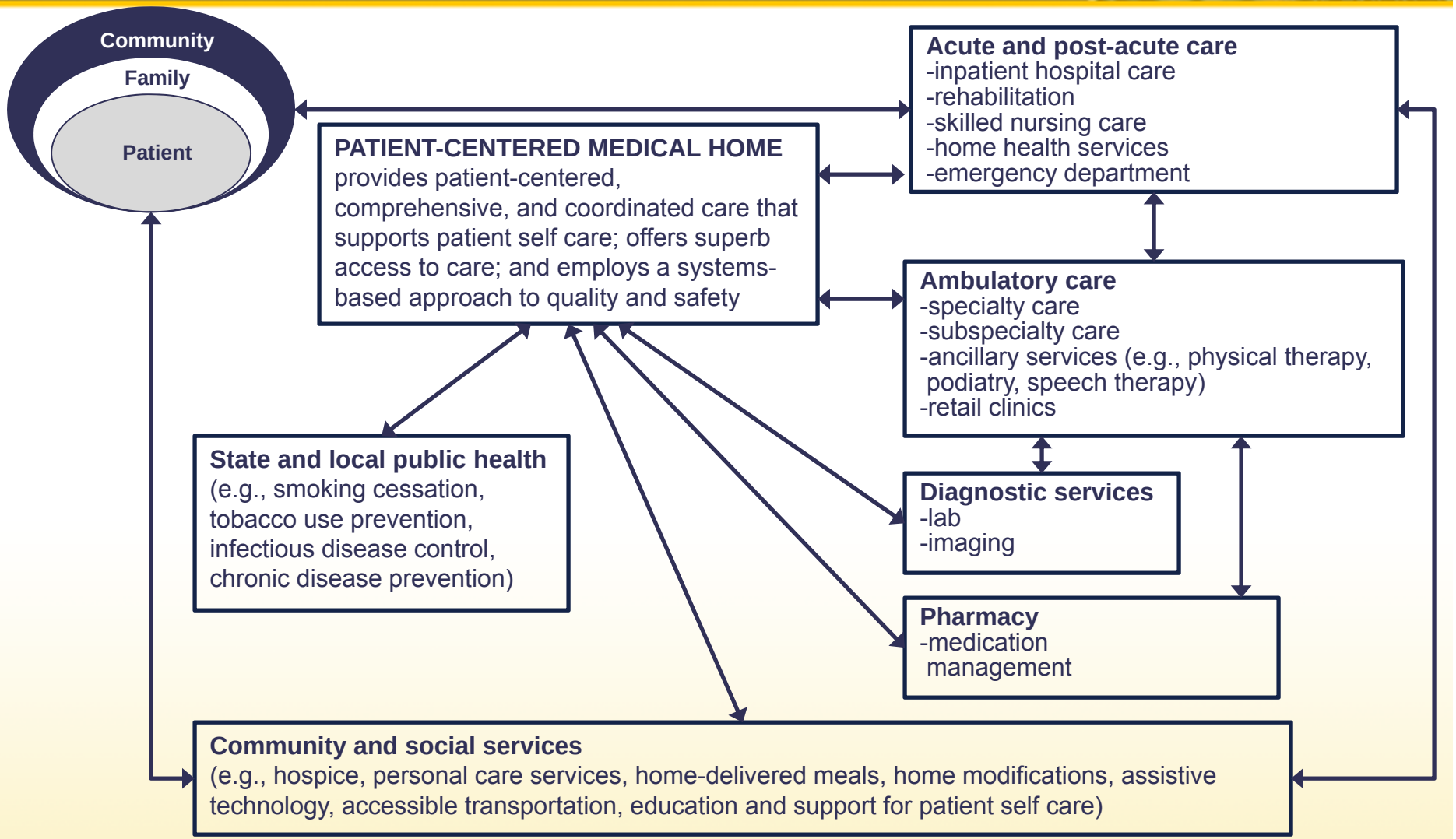
Emerging Care Models Provide the Coordination Necessary for Effective MS Management



- Coordinated care can be achieved by using approaches that include:
  - Teamwork
  - Care management
  - Medication management
  - Health information technology
- Managed care stakeholders can facilitate this coordination in various ways:
  - Establishing accountability and agreeing on responsibilities
  - Communicating/sharing knowledge
  - Assessing patients' needs and goals
  - Creating a proactive care plan
  - Monitoring and follow-up
  - Supporting patients' self-management goals
  - Linking to community resources
  - Working to align resources with patient and population needs

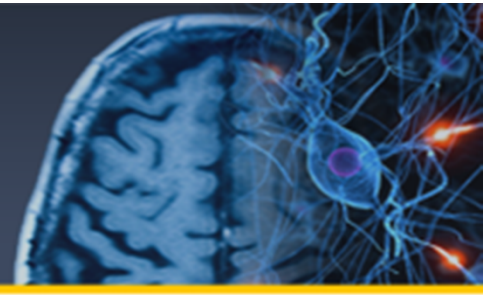
The PCMH Model and the Larger "Medical Neighborhood" is Aligned with Comprehensive Care in MS





AHRQ. Available at:
http://pcmh.ahrq.gov/sites/default/files/attachments/Coordinating%20Care%20in%20the%20Medical%20Neighborhood.pdf

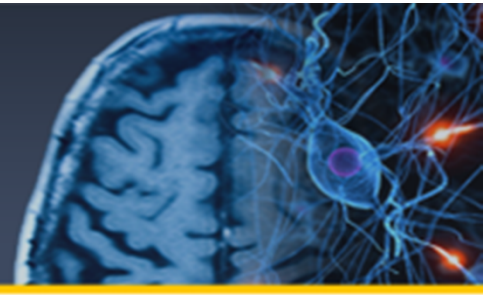
Adherence is a Key Concern in the Management of MS



- Between 17% and 40% of patients stop taking DMT within 1 year of initiation
- Multifactorial
  - Perceived lack of efficacy
  - Adverse effects
  - Depression
    - 41% of patients had new or increased depression within 6 months of treatment initiation
    - Decreased adherence in patients with depression

Rio J, et al. *Mult Scler*. 2005;11(3):306-309. Daugherty KK, et al. *J Am Pharm Assoc*. 2005;45(3): 371-375. Mohr DC, et al. *Arch Neurol*. 1997;54(5):531-533. Clerico M, et al. *J Neurol Sci*. 2007;259 (1-2):104-108.

Relationship between Nonadherence and Risk of Severe Relapse

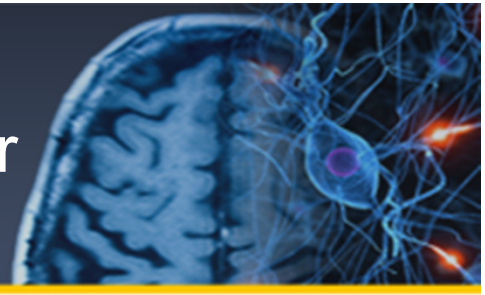


- MS patients who initiated DMT treatment (N=2388) were evaluated to examine the association between DMT adherence and severe relapse
- Adherence measures, including treatment gaps and MPR, were evaluated for 24 months following treatment initiation of a self-injectable DMT
  - Gaps in treatment of ≥90 days associated with increased risk of severe relapse relative to gaps of 0-10 days (OR=1.925; *P*=0.007)
  - Nonadherent patients (MPR <80%) 2x as likely to have a severe relapse (OR=1.976; 95% CI, 1.46-2.69) compared with adherent patients (≥80%)
- Findings of relationships between measures of adherence and severe MS relapse are associative and not causal

MPR = medication-possession ratio; OR = odds ratio.

Okuda DT, et al. Presented at: The Consortium of Multiple Sclerosis Centers 22nd Annual Meeting; May 28-31, 2008; Denver, Colorado. Abstract S55. Meletiche D, et al. Presented at: The Consortium of Multiple Sclerosis Centers 22nd Annual Meeting; May 28-31, 2008; Denver, Colorado. Abstract S47.

ACO and PCMH Models Can Address Adherence Issues at the Patient and Provider Levels



Patient Factors

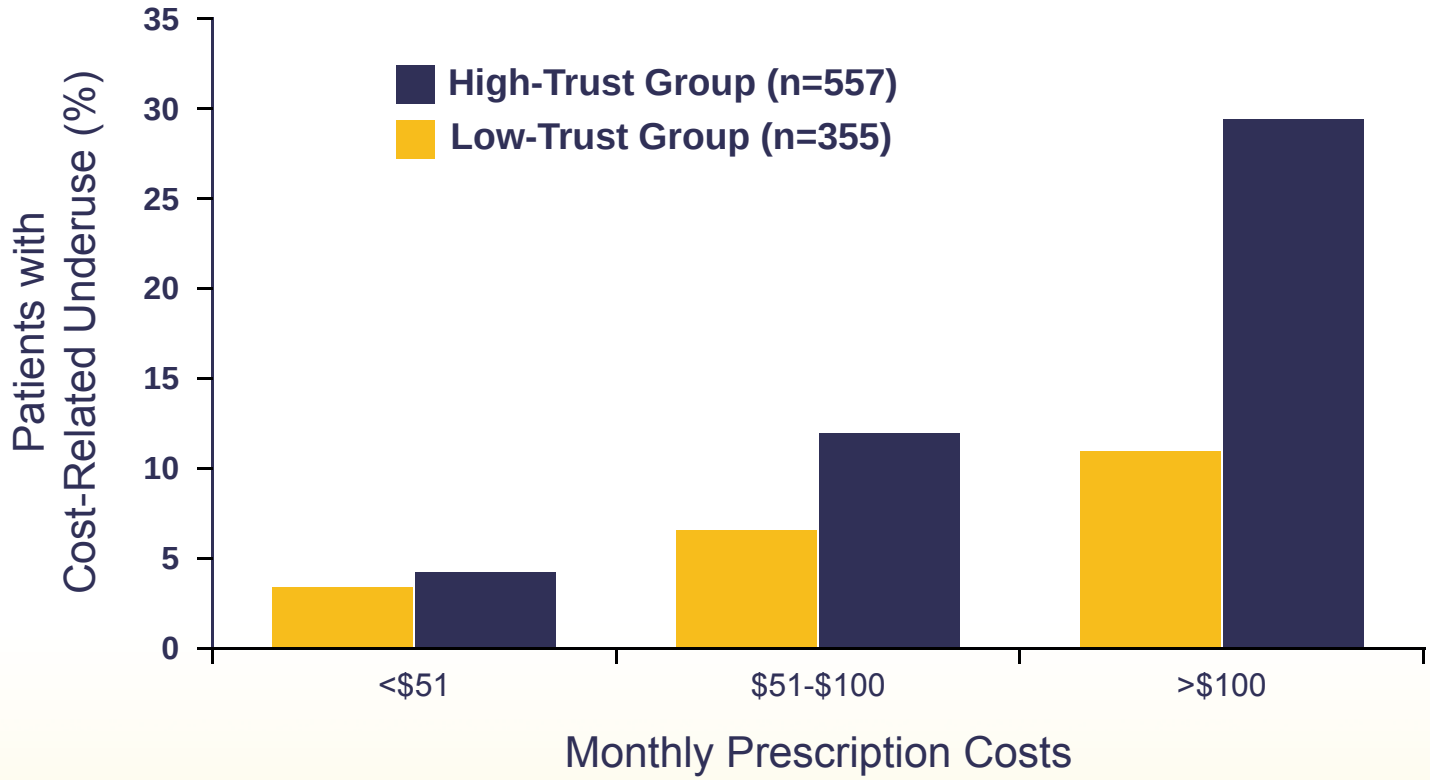
- Depression, anxiety, phobia
- Fatigue
- Cognitive status
- Patient attitude and beliefs (realistic therapeutic expectations)
- Active lifestyles
- Patient-physician relationship/teamwork

Physician Factors

- Lack of clear physician instructions
- Inappropriate patient education regarding expectations
- Lack of attention to side effects
- Limited access to care management support
- Reactive follow-up care

OT = occupational therapists; PT = physical therapists.

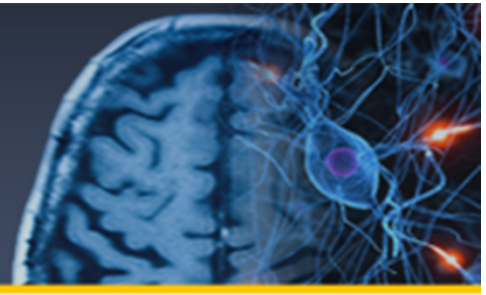
Patient-Provider Relationships Strengthened via the PCMH Model Can Improve Adherence Despite Rising Cost-Shares

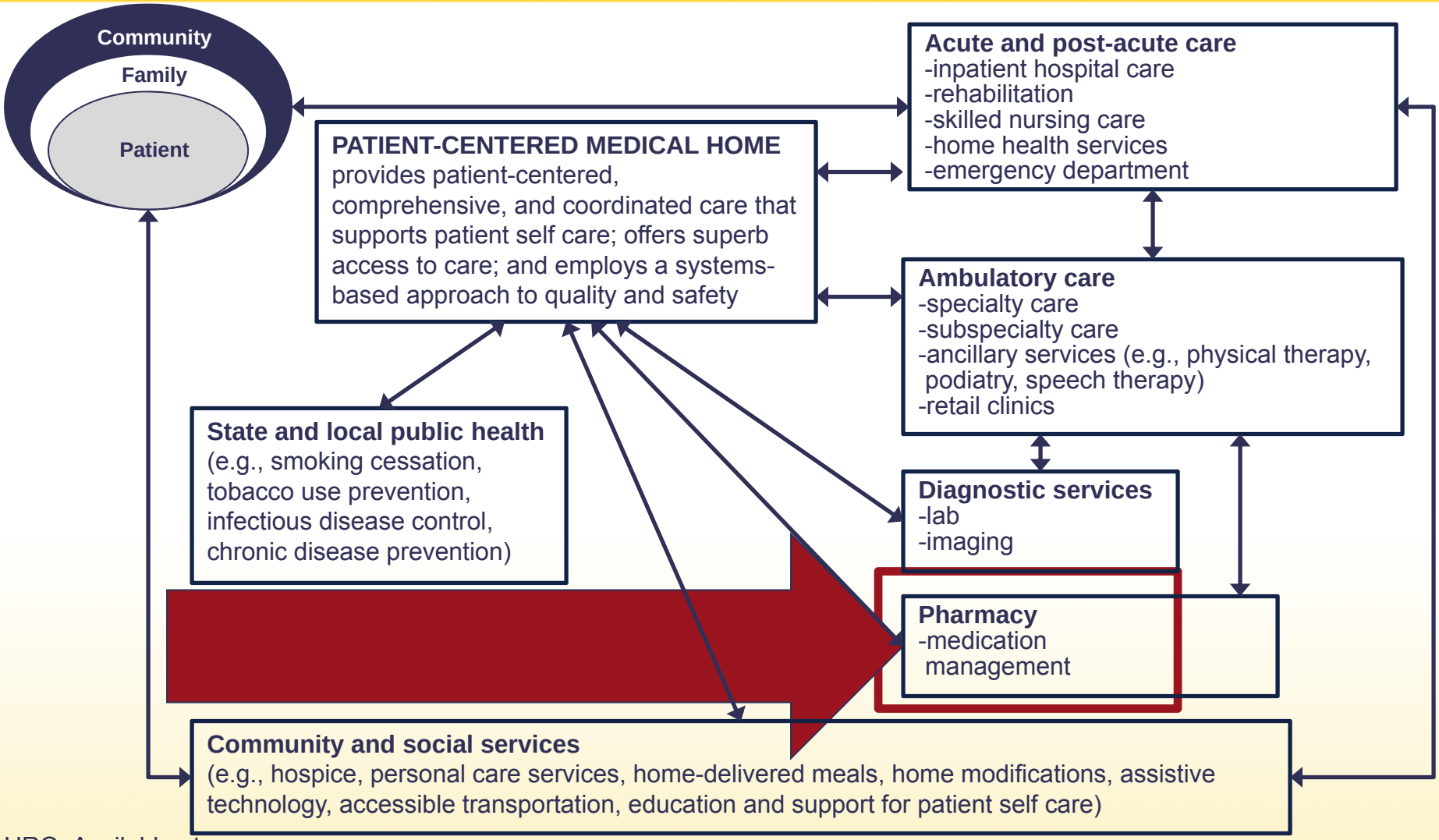


- As prescription costs increase, medication underuse increases
- In patients grouped by level of trust for their physician, the low-trust group was less likely to be adherent than the high-trust group

Piette JD, et al. *Arch Intern Med*. 2005;165(15):1749-1755.

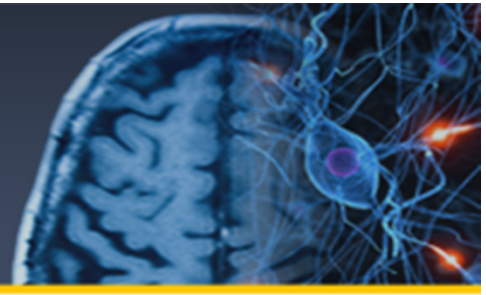
As Part of the Medical Neighborhood and ACOs, Pharmacy Management Services Serve to Address Adherence Issues in MS





AHRQ. Available at:
http://pcmh.ahrq.gov/sites/default/files/attachments/Coordinating%20Care%20in%20the%20Medical%20Neighborhood.pdf

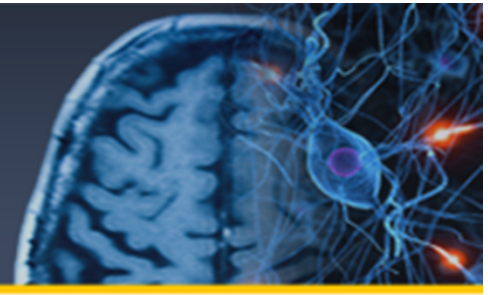
MTM Represents One Potential Pharmacy Service Employed by ACO and PCMH Models



- Through medication therapy management (MTM), steps can be taken to:
  - Target drug therapy problems
  - Establish focused medication management interventions
  - Develop a framework that is patient-centered
- Key factors:
  - Education
  - Setting expectations
  - Follow-up/evaluation

Turner AP, et al. *Rehab Psych*, 2014;59:136-146.

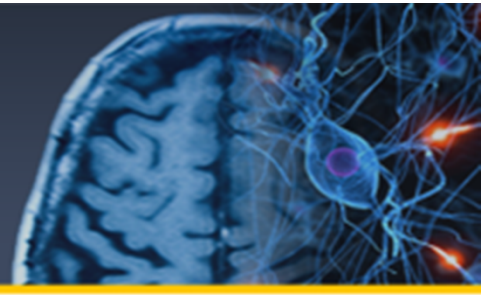
A PCMH Case Study: The Total Life Care Clinic



- The University of Texas Southwestern (UTSW) Medical Center hosts the Total Life Care (TLC) Clinic Every Monday
- At the TLC clinic, a multidisciplinary team meets with high-risk MS patients for the purpose of:
  - Discussing therapy goals and challenges
  - Reinforcing previous lessons
  - Performing global assessments to evaluate the patients
- Takes approximately 3-4 hours
- Patients are encouraged to return in 3-4 months for evaluation
- Once therapeutic and rehabilitative goals are achieved, patients “graduate” from the program

Logan D. Presented at the 2013 Annual Meeting of the Consortium of Multiple Sclerosis Centers.

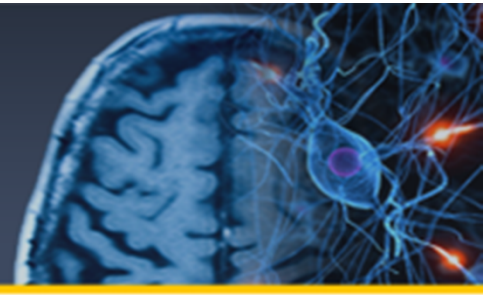
A PCMH Case Study: The Total Life Care Clinic (cont.)



- Outcomes are measured via the WHOQOL-BREF, an instrument that comprises 26 items in the following domains:
  - physical health
  - psychological health
  - social relationships
  - environment
- As of 2013, patients graduating from the TLC program did so after an average of 3.5 visits
- Quality of life was improved for physical health, psychological health, social relationships, and the environment based on WHOQOL-BREF measures

Logan D. Presented at the 2013 Annual Meeting of the Consortium of Multiple Sclerosis Centers.

Summary



- Recent healthcare reform legislation with an emphasis on value-based services and outcomes reporting
- The PCMH and ACOs represent emerging models in healthcare delivery that are aligned with changes resulting from healthcare reform
- These models of care also feature characteristics that are well suited for the management of MS in particular:
  - Emphasizing the role of the primary care physician
  - Coordination of care among a multidisciplinary team
  - Medication management and adherence-enhancing interventions
- Pilot programs incorporating the PCMH approach in the treatment of MS have demonstrated that these models can potentially improve the quality of care

Implementing Evidenced-Based Treatment Regimens, New Models of Care, and Patient Management Strategies for Multiple Sclerosis

Jointly provided by

PIM Postgraduate Institute for Medicine

Impact Education, LLC

This activity is supported by educational grants from Genzyme, a Sanofi company, Novartis Pharmaceuticals Corporation, and Teva Pharmaceutical Industries.

Implementing a Comprehensive MS Care Model: From Benefit Design to Specialty Pharmacy Management Services

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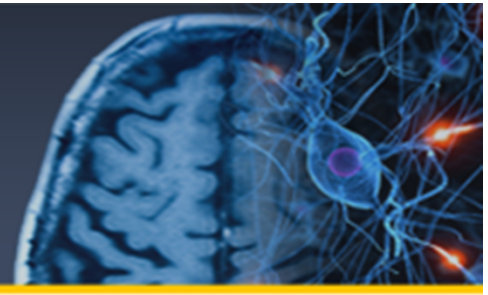
Faculty Disclosure



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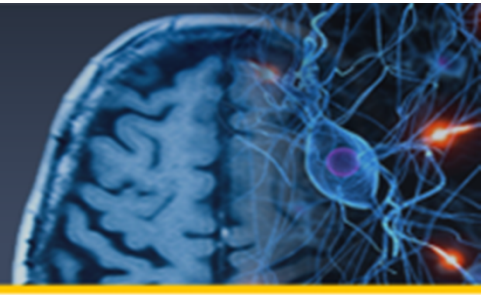
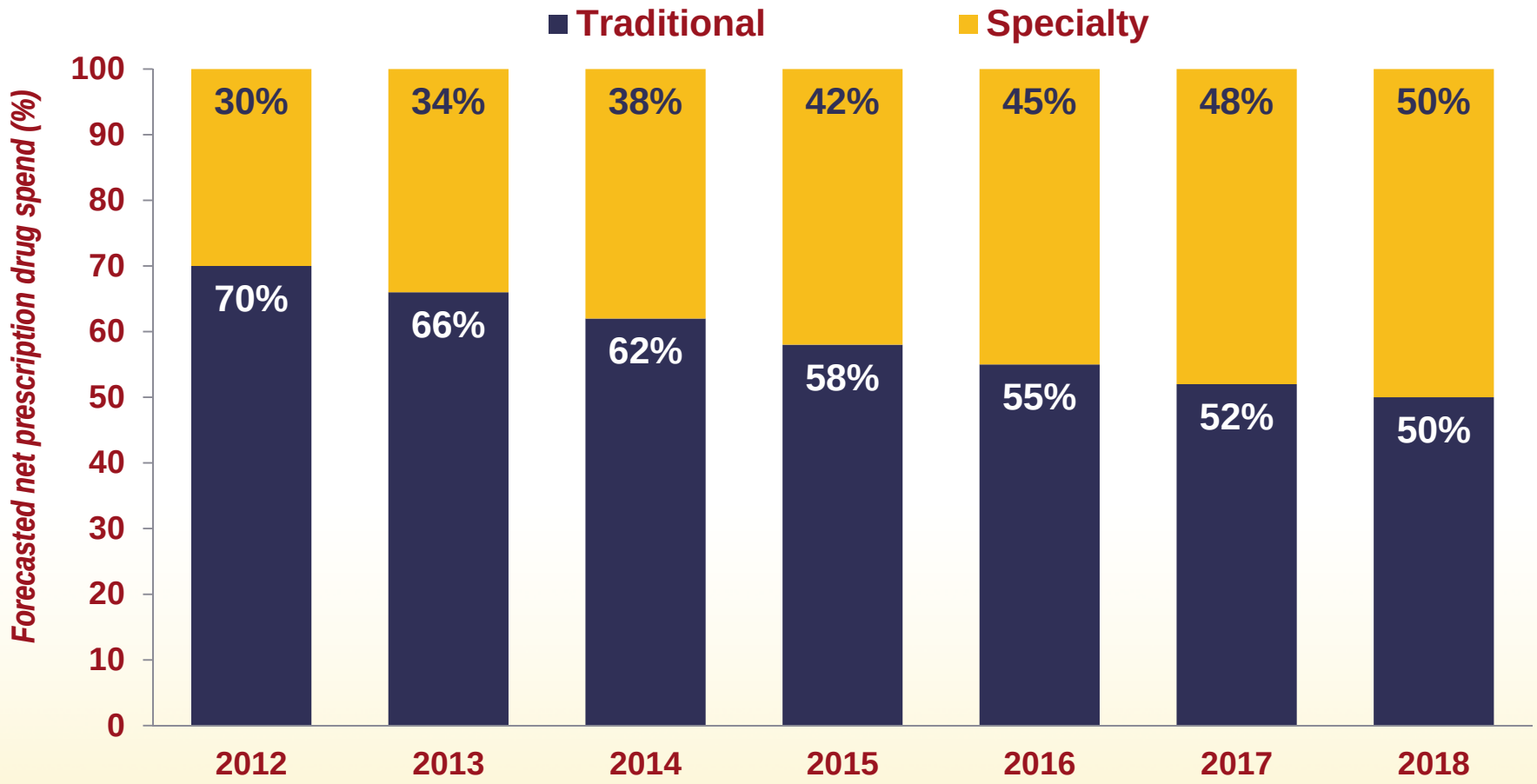
  Jeffrey D. Dunn, PharmD, MBA

  – *Consulting Fees:* Biogen Idec, Genzyme, a Sanofi Company, Teva Pharmaceutical Industries.

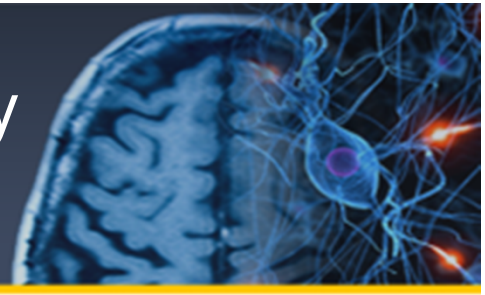
Growth of Spending on Specialty Drugs in Commercial Plans as Coverage Is Shifted Out of the Medical Benefit

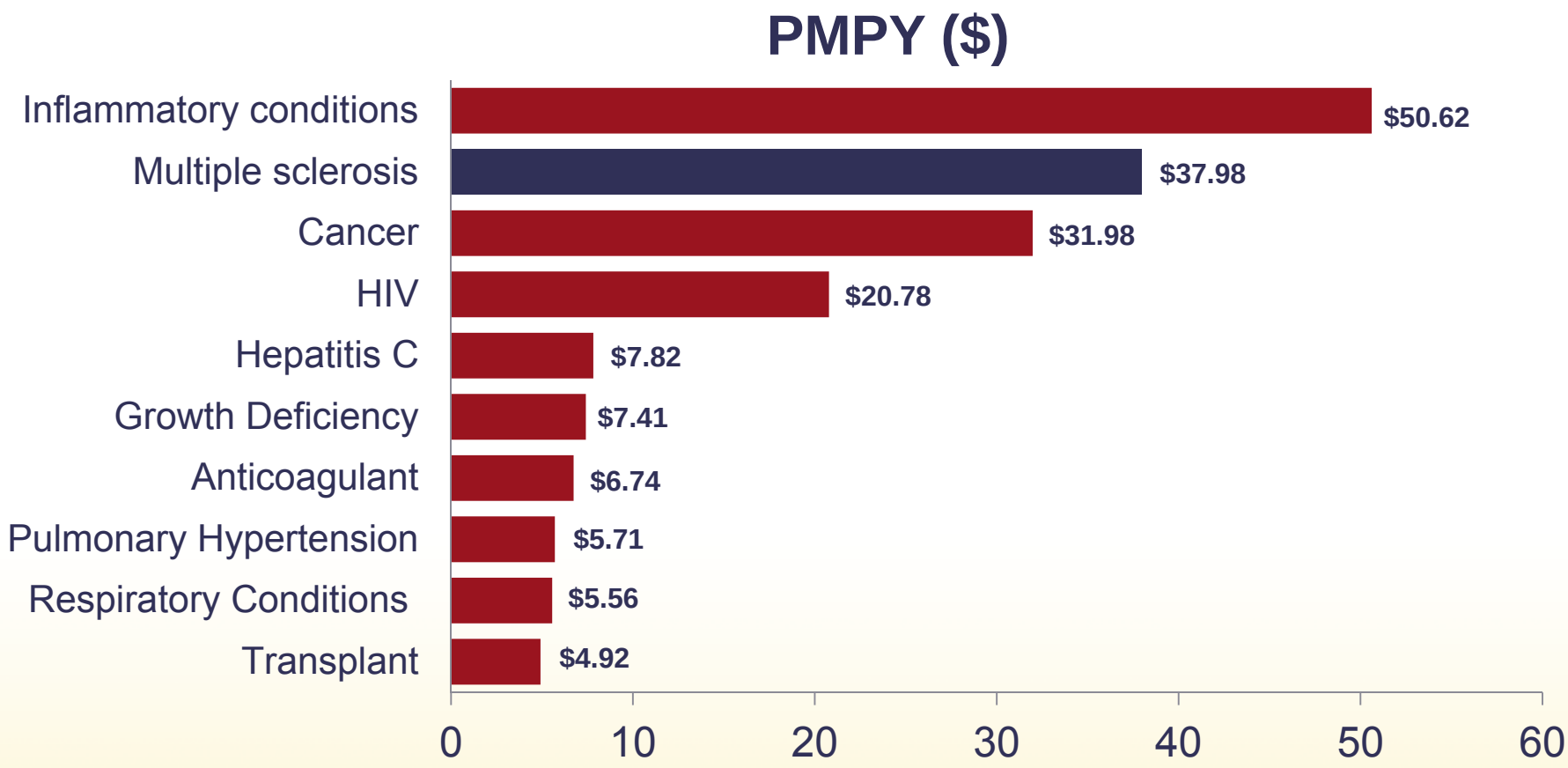




Artemetrx. Specialty drug trends across the pharmacy and medical benefit. 2013. http://www.artemetrx.com/docs/ARTEMETRX_Specialty_Trend_Rpt.pdf. Accessed 8/25/14.

MS is Second in Terms of PMPY Pharmacy Spend Among Specialty Categories

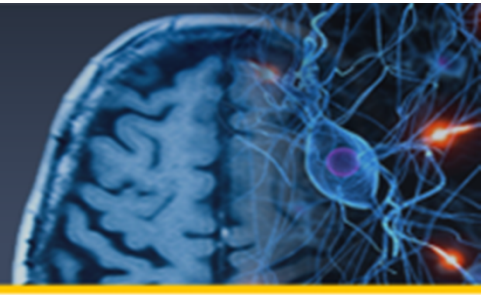




PMPY=per member per year.

Express Scripts. Drug Trend Report. 2013. http://www.drugtrendreport.com/commercial/specialty-trend-by-therapy-class.

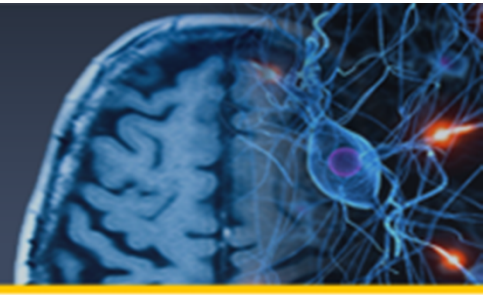
Accordingly, Stakeholders are Increasing their Attention to the MS Therapeutic Class



- Increasing cost trends are overwhelmingly the most commonly cited concern among managed care stakeholders with respect to specialty drugs
- Among the other top injectable drug priorities for stakeholders surveyed in 2013 were issues specifically related to the MS therapeutic class, including:
  - MS therapies
  - MS disease management interventions

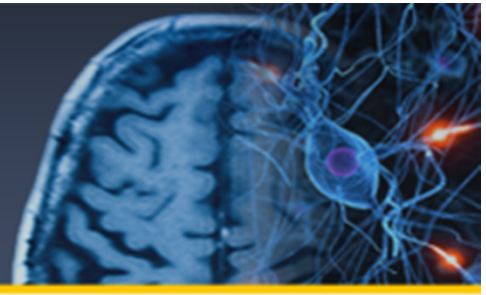
Magellan Rx Management. Medical Pharmacy Trend Report, 4th ed. 2013.

Current Trends in MS Specialty Management



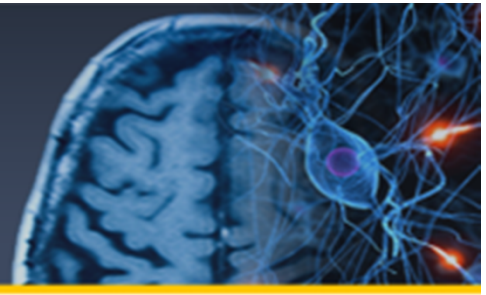
- Managed care is using traditional management strategies, customized for specialty medications
  - Prior authorization—78% of plans
    - Based on indication, monitor response, drive preferred, failure of other drug
  - Preferred products—63% of plans prefer MS drugs
    - National Drug Code block—19% of plans block nonpreferred
  - Cost sharing—27% of plans use tiered copay
  - Step edits—36% of plans use online edits
  - Mandatory specialty pharmacy provider
    - Pharmacy and medical benefit responsibility
  - Case/therapy management—22%, often by SPP
  - Cost-effectiveness analysis
  - REMS programs

Considerations for Specialty Pharmacy Management Strategies



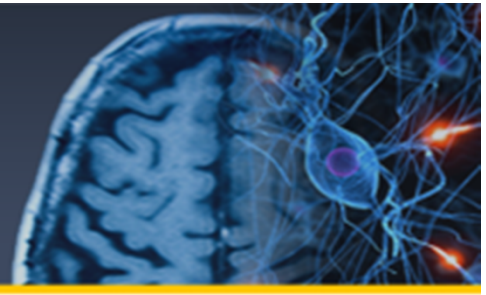
- Incentive programs
  - Member
  - Physician: differential reimbursement, pay for performance
- Specialty pharmacy integration
- Coordination/collaboration
  - Data management/widespread use of information technology
- Case management
  - Needs to be more active and educated
- Patient support programs
  - Mandatory?
  - Use of support programs provided by the drug manufacturer?
- Shared risk

MS Therapies Require a Multifaceted Approach Based on Benefit Design and Specialty Management



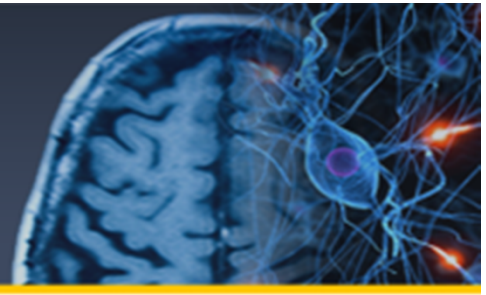
Benefit Design (Cost Share) & Formulary

Benefit Design/Formulary Management



- Tiering
- Cost-sharing
  - Tier four patient cost-sharing averages 25%
    - Can be much higher depending on the plan
  - Plans may provide for prior authorization for higher tier agents, but this is cumbersome for prescribers
- Contracting
  - Market baskets
- Out of Pocket (OOP)
  - Provide differential to members and physicians
  - By Rx, annual, etc.
- Align incentives
  - To providers and members
  - Between medical and pharmacy
- Close formularies
  - Based on CER
  - Deliver market share for lower costs

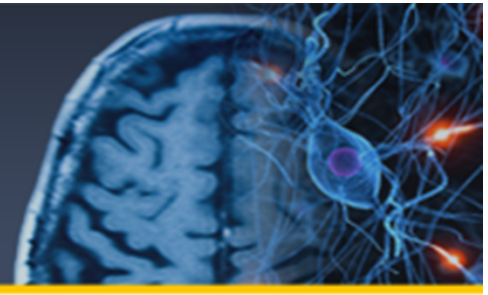
Potential Factors in MS Formulary Decision Making



HEDIS = Healthcare Effectiveness Data and Information Set; JCAHO = Commission on Accreditation of Healthcare Organizations; NCQA = National Committee for Quality Assurance; PBM = pharmacy benefit manager.

Academy of Managed Care Pharmacy. Format for Forumlary Submissions. Version 3.1. December 2012. http://www.amcp.org/practice-resources/amcp-format-formulary-submisions.pdf. Accessed August 22, 2014.

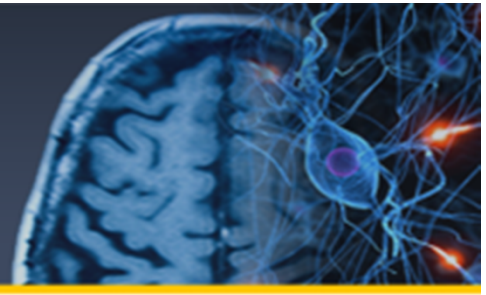
Goals of a Specialty Pharmacy Management Program



1. Equalize benefits between pharmacy and medical to avoid members choosing the administration site based on their coverage
2. Optimize cost management by receiving the lowest unit cost from dispensing pharmacies and receive any available rebates from manufacturers
3. Ensure appropriate use by employing clinical guidelines and criteria, prior authorization, and formulary programs
4. Improve clinical management by assessing and intervening on adherence and persistency, patient care services, therapy and case management, and demonstrating improved outcomes
5. Expertly craft the contract to account for changes in the industry, including generic biologics

Pharmaceutical Strategies Group. "Understanding Specialty Pharmacy Management."

Specialty Pharmacy Strategic Overview



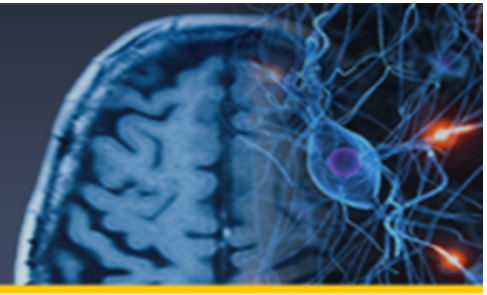
Specialty Strategy

- Program consists of four components focused on:
  1. Appropriate utilization
  2. Cost-savings
  3. Medical and pharmacy integration
  4. Increased transparency
- Program to be implemented in stages with each component complementing the other

Components

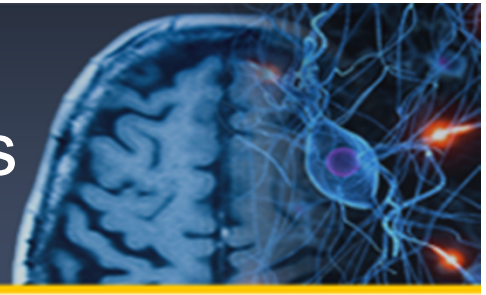
- Utilization Management
- Site of Care Optimization
- Drug Reimbursement Strategies
- Specialty Drug Management

Examples of Specialty Pharmacy Strategies



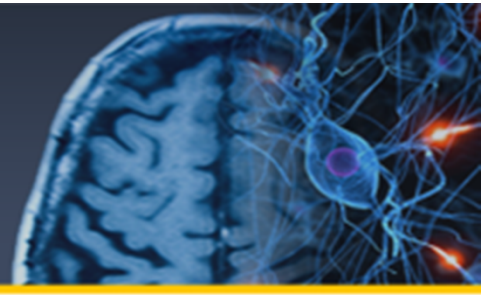
Strategy	Approach	Description
Benefit Management	▪ Specialty Formulary ▪ Tier Strategy	Multi-specialty tier formulary development
Utilization Management	▪ Utilization Edits (PA and QLs)	Add appropriate edits as drugs are launched and reviewed through the P&T committee
Specialty Pharmacy Tool	▪ J-code tool (e.g., Specialty Atlas) ▪ Medical vs. Pharmacy Benefit ▪ Retail, specialty, brown-bag	Tools to identify appropriate channel and incorporate pharmacy prior authorizations, MAC pricing, and quantity limits
MTM	▪ Specialty MTM ▪ Filling Specialty Pharmacy Void	Target programs include: Hepatitis C, MS, RA, and GH
Contracting	▪ Preferred products in key classes ▪ Medical and Pharmacy rebates	• Contract for additional rebates including: RA, MS, PAH, and GH • Continue to evaluate contracting opportunities in the specialty space

Objectives for Specialty Pharmacy Tools



- Identify appropriate medication channel for distribution
- Provide information to stakeholders on utilization management used on pharmacy benefit
- Facilitate coordination and communication between stakeholders

Utilization Management Tools - Medical



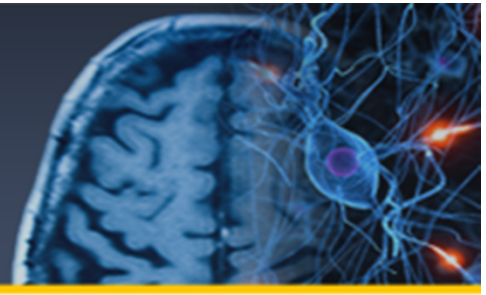
Quantity Limits

- Commonly used on pharmacy benefit
  - Mitigate waste and off-label use of high cost medications
- HCPCS units vary by drug leading to confusion and submission errors

Maximum Allowed Pricing

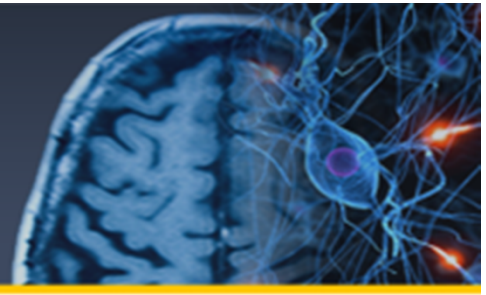
- Commonly used on the pharmacy benefit
  - Ensure appropriate reimbursement of medications with price fluctuations
  - Typically generic products

Care Management Strategies



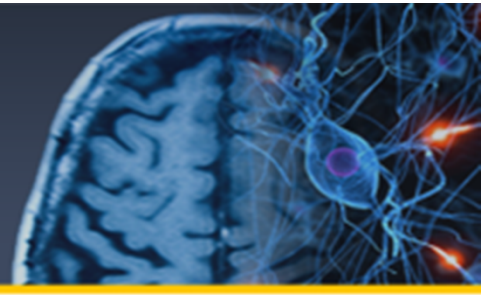
- Need a team of clinical professionals
  - Clinical Pharmacists
  - Nurse Case managers
  - Licensed Social Worker
- Members need help to navigate health care system
  - Serve as advocates
  - Identify most cost-effective site of care
  - Member education

Specialty Pharmacy MTM



- Need to fill the specialty pharmacy void
- Help eliminate barriers to care
- Increase adherence
- Recommended drug classes to be covered
  - Hepatitis C
  - *Multiple Sclerosis*
  - Inflammatory Diseases

Reimbursement Structures



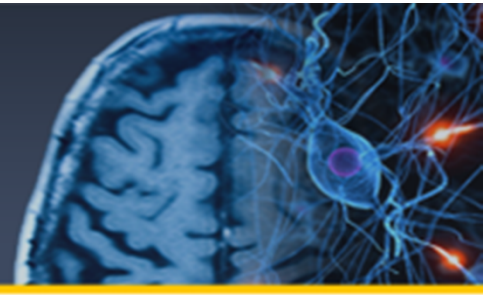
Pharmacy Benefit

- Traditionally medications are reimbursed to pharmacies using the drug's AWP minus a certain percentage

Medical Benefit

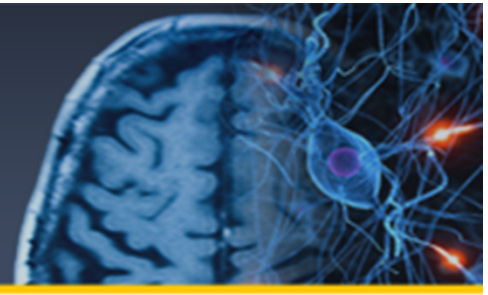
- Average Sales Price (ASP)
- Average Wholesale Price (AWP)
- Wholesale Acquisition Cost (WAC)
- Provider Capitation
- Percentage of billed charges

Multi-Specialty Tier Benefit Designs



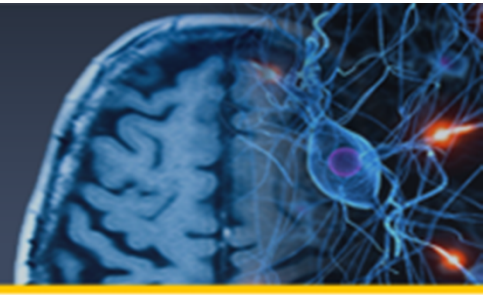
- Increasing number of generic products
- Biosimilars
- Preferred products
- Differentiation based on clinical efficacy and cost effectiveness

Future Considerations: Biosimilars



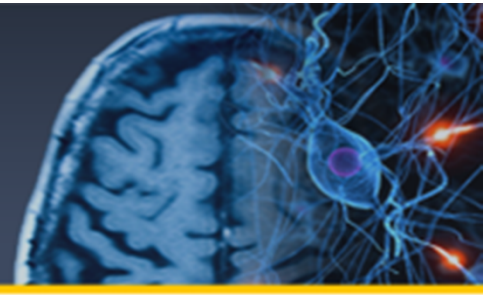
- Biosimilars provide a potentially positive incentive for insurers, managed care, and consumers paying out-of-pocket to minimize cost
  - Assumes costs of follow-on products will be lower
    - Or at least that there will be the ability of insurers, PBMs, etc. to negotiate
- Potential issues:
  - Rating / interchangeability
    - States to determine
    - Vs. batch variance???
    - Naming?
  - Data extrapolation / indications
  - Safety
  - Manufacturing
  - Cost
  - *Provider acceptance*
    - *Depends on disease state*
    - *Risk (financial vs. clinical)*
  - Experience
    - In Europe since 2006

Utilizing an Integrated P&T Committee



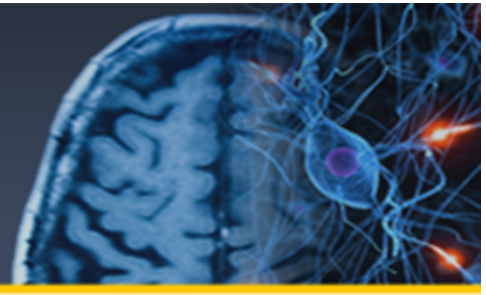
- Committee to evaluate specialty medications across both benefits
  - Identify appropriate distribution channel
  - Designate appropriate specialty tier placement
  - Evaluate medications that may traditionally be solely under medical benefit
- Results communicated via standardized announcements

Clinical Resource Role

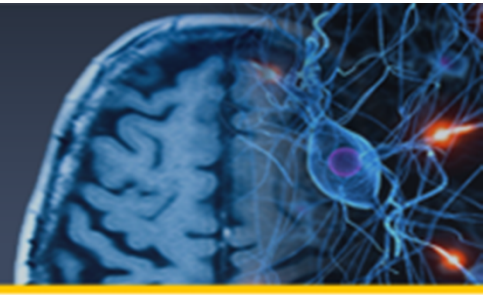


- Serve as clinical experts in working with providers in fee schedule development
- Serve as clinical liaison to health plans on specialty medications

Potential Efficiencies with Specialty Pharmacy Management



Summary



- MS therapies are a leading driver of the specialty drug spend, demanding increased attention from managed care stakeholders
- Stakeholders are challenged to devise a pharmacy benefit that strikes a balance between increasing patient out-of-pocket expenses and the risk of noncompliance
- An integrated approach that incorporates benefit design and formulary interventions in addition to specialty drug management is necessary to enact optimal clinical outcomes at a sustainable cost

Implementing Evidenced-Based Treatment Regimens, New Models of Care, and Patient Management Strategies for Multiple Sclerosis

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