Poster Number, Title, and Authors

#1: A model system to investigate axonal translation during cannabinoid induced long term depression	
Authors: Rebecca L. Bigler ¹ , Mark Niedringhaus ^{2,3} and Anne M. Taylor ^{2,3,4}	3
#2: The Impact of Disease-State-Specific Workgroups on Patient Satisfaction in a Startup Specialty Pharmacy within an Integrated Academic Health-System	4
Authors: Robin M. Guter, PharmD, MBA, RPh, BCPS;1 Chase O. Dye, CPhT, CCRP1	4
#3: Impact of the Clinical Therapy Management Program for Immune Globulin on Adherence for Patients at Barnes Precision Specialty Pharmacy	
Authors: Stacey Ness ¹ , John Ford ²	
#4: An Evaluation of Adherence Between Patients with Multiple Sclerosis (MS) Newly Initiating Treatment with a Self-Injectable or an Oral Disease-Modifying Drug (DMD)	6
Authors: Amy L Phillips, ¹ Molly Frean, ² Julie C Locklear, ¹ Joseph Menzin ²	6
#5 The Impact of Timing of Disease-Modifying Drug Treatment Initiation on Multiple Scleron Relapse Rates in Newly Diagnosed Patients	
Authors: Amy L Phillips, ¹ Juanzhi Fang, ¹ Frank A Corvino, ² David Oliveri ²	7
#6: Predictors of Adherence Using Panel Survey Data from Multiple Sclerosis Patients Currently Treated with High-Dose High-Frequency Interferons	8
Authors: Amy L Phillips, ¹ Chris M Kozma, ² Julie C Locklear ¹	8
#7: Real-World Assessment of Relapse, Medical Costs, and Persistency of Multiple Scleros Patients Treated with Subcutaneous Interferon Beta-1a	
Authors: Amy L Phillips, ¹ Julie C Locklear, ¹ Chris M Kozma ²	9
#8: Factors Associated with Early Disease-Modifying Drug (DMD) Treatment Initiation in Newly Diagnosed Patients with Multiple Sclerosis (MS)	10
Authors: Amy L Phillips, ¹ Natalie C Edwards, ² Molly Frean, ³ Julie C Locklear ¹	. 10
#9: Validation of a Novel Measure for Disease Severity of Multiple Sclerosis Using Real- World Data	11
Authors: Amy L Phillips, ¹ Michael A Munsell, ² Joseph Menzin ²	. 11
#10: The 2015 US Payor Landscape for Specialty Pharmacy: Results from a Survey of Medical and Pharmacy Directors	12
Authors: Richard A Brook; ^{1,2} Michael J. Sax; ³ , James (Jim) E Smeeding ^{1,4}	. 12
#11: Walgreens Local Specialty Pharmacies provide Convenient Access to Oral Chemotherapies for Patients throughout the United States	13
Authors: Francis Staskon, PhD¹; Nicole Leiter, PharmD¹; Heather Kirkham, PhD, MPH¹	
#12: Quality of Life, Depression, Anxiety, and Medication Adherence among Patients with Cystic Fibrosis using Pharmacy Management Services	14
Authors: Heather Kirkham, PhD, MPH¹; Francis Staskon, PhD¹; Nishita Hira, PharmD²; Darren McLane, PharmD²	. 14



#13: Descriptive Study of Patients on Infertility Treatments using Walgreens Pharmacies	15
Authors: Julia Zhu, MPH¹; Kajaal Patel, RPh²; Ann Scalia, RN, BSN, CNOR²; Rick Miller, BS, MBA²; and Heather Kirkham, PhD, MPH¹	15
#14: The Effect of a Multidisciplinary Healthcare Team on Patient Outcomes in Patients Receiving Chemoradiation for Head and Neck Cancers	16
Author: Shannon Gowen ¹	16
#15: Retrospective analysis of the medication utilization and clinical outcomes of patients treated with various regimens for hepatitis C infection.	17
Authors: William D. Trombatt, PharmD ^{1,2} , Pamela H. Koerner, BS, PharmD, BCPS ¹ , Zoie N. Craft, BA ² , Richard T. Miller, RPh, MBA, CSP ² , Khalid M. Kamal, MPharm, PhD ¹	17
#16: In Early RA SWEFOT Patients with Non-Response to Methotrexate Monotherapy the Change in Multibiomarker Disease Activity Score is Differentially Associated With Subsequent Response to Non-Biological Versus Biological Therapy	18
Authors: Karen Hambardzumyan ¹ ; *Rebecca Bolce ² ; Saedis Saevarsdottir ³ ; Kristina Forslind ^{4;} Ingemar F. Petersson ⁴ ; Pierre Geborek ⁴ ; Sofia Ernestam ⁵ ; Eric H. Sasso ² ; David Chernoff ² ; Scott E. Cruickshank ⁶ ; Ronald F. Van Vollenhoven ¹	18
#17: Recent Cost Trends in Patients Using Biologic Therapies for the Treatment of Psoriasis	
Authors: Andreas Kuznik ¹ ; Sergio Eslava ² ; John Cai ²	19



#1: A model system to investigate axonal translation during cannabinoid induced long term depression

Authors: Rebecca L. Bigler¹, Mark Niedringhaus^{2,3} and Anne M. Taylor^{2,3,4}

- ¹Curriculum in Genetics and Molecular Biology, UNC-Chapel Hill, Chapel Hill, NC
- ²UNC/NC State Joint Department of Biomedical Engineering, UNC-Chapel Hill, Chapel Hill, NC
- ³Neuroscience Center, UNC-Chapel Hill, Chapel Hill, NC
- ⁴Carolina Institute for Developmental Disabilities, UNC-Chapel Hill, Chapel Hill, NC

Email Address for Correspondence: rlprocto@email.unc.edu

Our **objective** was to develop an in vitro system of axon-autonomous endocannabinoid induced long term depression of neuron excitability (eCB-LTD) and investigate the role of local protein synthesis in this form of synaptic plasticity. Endocannabinoids are released by the postsynapse and bind presynaptic cannabinoid receptors to influence presynaptic excitability and facilitate learning and memory. This effect has been shown to depend on protein synthesis within the presynaptic axon but few details of the proteins synthesized or the mechanisms involved are known. The presence of the large postsynaptic structure is a significant impediment when evaluating the fine presynaptic structure. We have developed methods to overcome this challenge. To produce axon-autonomous hemi-synapses we cultured embryonic rat neurons in 2-compartment axon-isolating microfluidic chambers. After 9 days in culture we applied poly-D-lysine coated latex beads, which temporarily simulate a postsynaptic target, to the sequestered axons. To induce eCB-LTD we applied low frequency stimulation (1Hz, 5 minutes) in the presence of the potent cannabinoid receptor agonist WIN 55,212-2 (5µM) on day 10 in culture. We measured vesicle release kinetics and the spatial organization of presynaptic proteins three hours later. Our results establish that LTD was induced in our hemi-synapse system. We showed that presynaptic clustering of β-catenin, a protein locally synthesized during synapse formation and implicated in memory consolidation, increased after induction of eCB-LTD. We conclude that eCB-LTD can be induced in the absence of a biological postsynaptic structure allowing investigation of local presynaptic mechanisms. We hypothesize that local synthesis of β-catenin is involved in establishing or maintaining eCB-LTD. With this system we can evaluate the mechanisms of translational regulation involved in endocannabinoid induced long term depression.

Disclosures: A.M.T. is an inventor of the microfluidic chambers (US 7419822 B2) and has financial interest in Xona Microfluidics, LLC. R.L.B. and M.N. declare no competing financial interests.

#2: The Impact of Disease-State-Specific Workgroups on Patient Satisfaction in a Startup Specialty Pharmacy within an Integrated Academic Health-System
Authors: Robin M. Guter, PharmD, MBA, RPh, BCPS;¹ Chase O. Dye, CPhT, CCRP¹
¹Cleveland Clinic, Cleveland, Ohio

Email Address for Correspondence: GUTERR@ccf.org

Objective: To show the direct correlation between patient-centered care from a disease-state-specific clinical pharmacy team and patient experience regarding their specialty pharmacy service

Methods: Voluntary postal mail questionnaire/survey was distributed to enrolled patients and was returned via prepaid envelope. Surveys contained eight questions based upon a fourpoint Likert scale.

Results:

Welcome Packets distributed (January to June 2015): 734

Surveys returned (n=): 131

Response rate: 17.85%

Aggregate patient satisfaction Q1 2015: 97.99% Aggregate patient satisfaction Q2 2015: 98.51%

Conclusion: Customized care provided by each disease-state team resulted in patients receiving a concierge-like service that can be associated with a positive experience and elevated satisfaction scores. Due to the dedicated support resources assigned to each patient, experience outcomes were found to be favorable as seen by the voluntary comments provided by patients upon survey, whereas, specific names of their team members were documented by the patient.

Disclosures: The authors have no conflicts or disclosures related to this publication.

#3: Impact of the Clinical Therapy Management Program for Immune Globulin on Adherence for Patients at Barnes Precision Specialty Pharmacy

Authors: Stacey Ness¹, John Ford²

¹Managed Health Care Associates (MHA), Florham Park, NJ.

Email Address for Correspondence: sness@mhainc.com

Introduction Clinical product variations, administration considerations, patient monitoring, reimbursement challenges, and increasing data needs of all stakeholders must be considered when managing the Immune Globulin (IG) population.

Rationale In order to meet the needs of multifaceted stakeholders, Barnes Precision Specialty Pharmacy implemented MHA's Clinical Therapy Management (CTM) program to track IG patients. CTM allows clinicians to follow a clinical support pathway and to facilitate the collection of clinical and dispensing metrics.

Methods Barnes implemented the professionally peer reviewed CTM program in September 2014. 178 patients who had at least one prescription dispensed for IG therapy in either of the study periods (6 months pre-CTM and 6 months post-CTM) were included. Adherence for IG therapy was measured by average number of fills per patient and total number of fills prior to CTM implementation and post-CTM implementation. The average number of grams per patient in each of the study periods were also analyzed.

Results The total number of fills prior to the CTM program was 696 compared to 943 after implementation. The average number of fills prior to the CTM program was 3.91 compared to 5.3 after implementation (p=0.001). The average number of grams increased from 168.54 grams in the first study period to 246.29 grams per patient post CTM implementation (p=0.015).

Conclusions Implementation of the CTM program had a significant impact on adherence. Average number of grams per patient also increased significantly in this study. Data on how this may have impacted clinical outcomes is yet to be determined and further analysis needs to be done to characterize the patient population, dosing, and outcomes. The CTM program is one strategy that Barnes Precision Specialty Pharmacy uses to manage a complex therapeutic category and work towards visibility into actionable clinical data, optimal patient outcomes, and excellent customer service to all stakeholders.

Disclosures: None.

²Barnes Precision Specialty Pharmacy, Valdosta, GA.



#4: An Evaluation of Adherence Between Patients with Multiple Sclerosis (MS) Newly Initiating Treatment with a Self-Injectable or an Oral Disease-Modifying Drug (DMD)

Authors: Amy L Phillips, 1 Molly Frean, 2 Julie C Locklear, 1 Joseph Menzin 2

¹EMD Serono, Inc., Rockland, MA, USA;

Email Address for Correspondence: Amy.Phillips@emdserono.com

Objective: To evaluate medication adherence in MS patients newly initiating treatment with a self-injectable or oral DMD.

Methods: MS patients (aged 18–63 years; ≥1 medical claim with MS diagnosis [ICD-9-CM:340.xx]) with ≥1 DMD claim (first claim=index date), continuous eligibility 12 months preand post-index, and no DMD claim during pre-index were identified from IMS LifeLink Plus database from 7/1/2010 to 6/30/2014. Patients were grouped by self-injectable versus oral DMD. Fisher and Wilcoxon tests were used in unadjusted statistical comparisons. Logistic regression was used to evaluate likelihood of adherence (12-month post-index medication possession ratio [MPR]=≥0.8) to index DMD group. Covariates included age, sex, and baseline comorbidities.

Results: The analysis included 7207 self-injectable and 1175 oral DMD patients (mean age: 43.0 vs 44.9 years; p<0.0001). Unadjusted analyses: mean MPR was greater in the self-injectable (0.69) versus oral (0.68) DMD group (p=0.0002). No difference in percentage of patients ≥0.8 MPR was observed (54.1% vs 53.0%; p=0.5075, respectively). Patients in the self-injectable group (9.9%) were more likely to switch than patients in the oral group (6.6%; p=0.0003); no differences were observed in proportion of patients discontinuing (26.6% vs 28.2%; p=0.2710), time to discontinuation (mean number of days: 118.0 vs 113.7; p=0.1341), or time to switch (mean number of days: 163.1 vs 153.1; p=0.2519), respectively. Index DMD was not a significant predictor of adherence (p=0.3473). Male sex and older age groups (vs 18–34) were associated with significantly higher likelihood of adherence (odds ratios [ORs] 1.20 and 1.22–1.33, respectively; p<0.01). Depression was associated with lower likelihood of adherence (OR 0.62; p<0.0001).

Conclusions: There was no difference in adherence attributable to route of administration. Male sex and older age were associated with higher likelihood of adherence, while depression was associated with lower likelihood of adherence.

Disclosures: Study sponsored by EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany) and Pfizer Inc, New York, NY, USA. ALP and JCL are employees of EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany). MF and JM are employees of Boston Health Economics, which receives funding from the study sponsor, EMD Serono.

²Boston Health Economics, Inc., Waltham, MA, USA



#5 The Impact of Timing of Disease-Modifying Drug Treatment Initiation on Multiple Sclerosis Relapse Rates in Newly Diagnosed Patients

Authors: Amy L Phillips, 1 Juanzhi Fang, 1 Frank A Corvino, 2 David Oliveri2

¹EMD Serono, Inc., Rockland, MA, USA;

Email Address for Correspondence: Amy.Phillips@emdserono.com

Objective: To evaluate whether early or late disease-modifying drug (DMD) treatment initiation is associated with improved outcomes in multiple sclerosis (MS; ie, relapse rates).

Methods: A retrospective analysis of a large US electronic health records database was utilized to evaluate newly diagnosed MS patients from 1/1/2007 to 8/302014 (index date=date of first recorded MS diagnosis [ICD-9 code 340.XX]). Patients were required to have ≥1 year of continuous baseline (pre-index) enrollment to ensure cases were newly diagnosed, plus 2 years of continuous enrollment following index. Early and late DMD initiators were defined as patients receiving DMD therapy within 90 days and >90 days following index, respectively. Relapse was determined by the presence of MS-related hospitalization or MS diagnosis in an outpatient setting followed by a corticosteroid prescription within 7 days. Relapses were assessed within the 2-year time horizon following index. Chi-square test was conducted to evaluate statistical significance of relapse rates between early and late initiator groups. Baseline demographics and Charlson Comorbidity Index (CCI) scores were evaluated.

Results: 4732 eligible MS patients were identified during the study period: 2042 initiated early DMD therapy; 2690 initiated delayed DMD therapy. Average time to DMD treatment: 20.9 ± 27.6 days (early initiators); 346.3 ± 181.1 days (late initiators). A higher rate of relapse was found among patients initiating late DMD therapy; 19.7% of early initiators (n=403) experienced a relapse, compared with 22.6% of late initiators (n=609; p=0.0158) in the 2 years post index. Similar mean age (46.9 years at index for both groups) and CCI scores (early initiators: 0.3, late initiators: 0.32) were observed between cohorts at baseline.

Conclusions: Results suggest early initiation of DMD treatment may be associated with lower likelihood of relapse in MS patients. Given the chronic nature of MS, timing of therapy may impact the long-term outcomes of MS patients.

Disclosures: This study was sponsored by EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany) and Pfizer Inc, New York, NY, USA. ALP and JF are employees of EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany). FAC and DO are employees of Genesis Research, Hoboken, NJ, USA.

²Genesis Research, LLC, Hoboken, NJ, USA



#6: Predictors of Adherence Using Panel Survey Data from Multiple Sclerosis Patients Currently Treated with High-Dose High-Frequency Interferons

Authors: Amy L Phillips, 1 Chris M Kozma, 2 Julie C Locklear 1

¹EMD Serono, Inc., Rockland, MA, USA;

Email Address for Correspondence: Amy.Phillips@emdserono.com

Objective: To evaluate the relationship between treatment with high-dose, high-frequency interferons and adherence among patients with multiple sclerosis (MS).

Methods: A random sample of relapsing-remitting MS patients (age ≥18 years, clinical trialnaïve) from the US National Health and Wellness Survey or Lightspeed Research panel completed an Internet survey in November/December 2012. Adherence was evaluated among those indicating current treatment (≥4 months) with subcutaneous interferon beta-1a (scIFNβ1a) three times weekly (tiw) or subcutaneous interferon beta-1b (scIFNβ1b) every other day (eod). Adherence was measured using the 4-item Morisky Medication Adherence Scale (forget to take medication, careless at times about taking, stop if better, stop if worse; high adherence = all negative responses). Baseline characteristics were compared using Chisquare and t-tests. Logistic regression evaluated the relationship between scIFNβ1a or scIFNβ1b treatment and the odds of having high adherence. Covariates included age, sex, exercise, and therapy-related variables (months on therapy, satisfaction, perception of effectiveness, cost).

Results: Of 969 surveyed, 80 sclFN β 1a and 63 sclFN β 1b patients met inclusion criteria (mean [standard deviation] age: 49.0 [10.4] years, 88.8% female vs 51.3 [8.7] years, 87.3% female, respectively; p-values >0.05). A greater percentage of sclFN β 1a patients reported high adherence compared with sclFN β 1b patients (58.8% vs 33.3%; p=0.0025). After adjusting for covariates, sclFN β 1a patients had a greater odds of high adherence (odds ratio [OR] 2.92; p=0.0101). Male sex (OR 4.37; p=0.0297), time since last relapse (years; OR 1.04; p=0.0483), frequent exercise (OR 1.06; p=0.0094), and Patient-Determined Disease Steps score (OR 1.34; p=0.0110) were predictive of high adherence.

Conclusions: In this exploratory analysis, treatment with sclFNβ1a tiw was strongly associated with high adherence relative to sclFNβ1b eod.

Disclosures: Study sponsored by EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany) and Pfizer Inc, New York, NY, USA. ALP and JCL are employees of EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany). CMK is a consultant who is paid for by EMD Serono, Inc. and Pfizer Inc.

²Independent Research Consultant, Saint Helena Island, SC, USA



#7: Real-World Assessment of Relapse, Medical Costs, and Persistency of Multiple Sclerosis Patients Treated with Subcutaneous Interferon Beta-1a

Authors: Amy L Phillips, 1 Julie C Locklear, 1 Chris M Kozma²

¹EMD Serono, Inc., Rockland, MA, USA;

Email Address for Correspondence: Amy.Phillips@emdserono.com

Objective: To describe relationships among persistency with subcutaneous interferon beta-1a (scIFN β 1a), relapse timing relative to discontinuation, and medical costs in patients with multiple sclerosis (MS).

Methods: Patients (aged 18–63 years) with ≥1 MS claim (ICD-9-CM:340.xx) and an initial scIFNβ1a claim (index event), 12 months of continuous eligibility before and 24 months after index were identified in the IMS PharMetrics Plus[™] database. Discontinuation was defined as a ≥90 day gap in scIFNβ1a therapy. Relapse was defined as the first post-index MS-related inpatient stay, emergency room visit or MS outpatient visit with a corticosteroid claim ± 7 days. Relapses were categorized as before or after scIFNβ1a discontinuation. Medical costs (excluding disease-modifying drug [DMD] costs) per day (US\$) pre or post discontinuation of scIFNβ1a are presented. Costs were evaluated with generalized linear regression models using gap, time of first relapse and the interaction as predictors. Prior costs, age, sex, and time to relapse were evaluated as covariates.

Results: 1540 MS patients met the study criteria; 4% had a relapse and 50% (n=770) discontinued sclFN β 1a during follow-up. Patients discontinuing sclFN β 1a averaged 250 (standard deviation [SD]=182) days of treatment (33.1% relapsed), while those who did not discontinue averaged 726 (SD=15) days of treatment (25.2% relapsed; p<0.01). Non-DMD medical cost/day was lowest for patients with no gap and no relapse (\$24.71/day). Patients who discontinued sclFN β 1a and had their first relapse after discontinuation had non-DMD medical costs of \$39.04/day prior to discontinuation and \$52.29/day after discontinuation. Patients with no gap and a relapse while sclFN β 1a was available had lower non-DMD medical costs (\$38.88/day) than patients with a gap in sclFN β 1a who experienced a relapse while on treatment (\$72.37/day). Models suggest that costs differ depending on gap status and timing of the relapse relative to sclFN β 1a discontinuation (p<0.01).

Conclusions: These results suggest the value of maintaining scIFNβ1a treatment.

Disclosures: Study sponsored by EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany) and Pfizer Inc, New York, NY, USA. ALP and JCL are employees of EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany). CMK is a consultant who is paid for by EMD Serono, Inc. and Pfizer Inc.

²Independent Research Consultant, Saint Helena Island, SC, USA



#8: Factors Associated with Early Disease-Modifying Drug (DMD) Treatment Initiation in Newly Diagnosed Patients with Multiple Sclerosis (MS)

Authors: Amy L Phillips, 1 Natalie C Edwards, 2 Molly Frean, 3 Julie C Locklear 1

¹EMD Serono, Inc., Rockland, MA, USA;

²Health Services Consulting Corporation, Boxborough, MA, USA;

³Boston Health Economics, Inc., Waltham, MA, USA

Email Address for Correspondence: <u>Amy.Phillips@emdserono.com</u>

Objective: Evaluate whether age, sex, region, comorbidity, and diagnosis year were associated with early DMD treatment initiation in newly diagnosed MS patients.

Methods: Retrospective analysis of newly diagnosed MS patients receiving ≥1 DMD within 2 years of diagnosis derived from a national, commercial US managed care database. Logistic regression model was used to predict early DMD treatment initiation (defined as having a DMD claim within 60 days of MS diagnosis). Explanatory variables included were age group (18–34, 35–44, 45–54, 55–65 years), sex, baseline comorbidity index (Charlson Score 0, 1, or ≥2), region (Midwest, South, Northeast, West), and diagnosis year (2008–2012).

Results: 7621 MS patients met study inclusion criteria. Average age was 41.6 years (standard deviation [SD]=10.4); 74.5% were female. Most patients were from the Midwest (34.0%) or South (31.9%), reflective of the national database sampling used in this study. Average time from first MS diagnosis to first DMD was 128.3 days (SD=164.3); median time to treatment was 56 days. Examining time to first treatment by 30-day increments demonstrated that 28.9% of patients received their first DMD in <30 days, and roughly half of patients (52.4%) received treatment within 60 days (n=3995). The model showed that older age groups (vs 18–34 year group; odds ratios [ORs] 0.70–0.89; p<0.05) and patients living in the Northeast (vs Midwest; OR 0.87; p=0.023) were less likely to initiate a DMD within 60 days. Male patients, patients (OR 1.14; p=0.013) with a higher Charlson comorbidity score (≥2 vs 0; OR 1.23; p=0.018), and patients who received an MS diagnosis in 2010 (OR 1.21; p=0.007) were more likely to initiate a DMD within 60 days.

Conclusions: Older age, male sex, greater comorbidity, Northeast region, and 2010 diagnosis year were associated with DMD treatment initiation within 60 days of diagnosis.

Disclosures: Study supported by EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany) and Pfizer Inc, New York, NY, USA. ALP and JCL are employees of EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany). NCE received personal compensation as a Health Services Research consultant. MF is an employee of Boston Health Economics, which receives funding from the study sponsor, EMD Serono.



#9: Validation of a Novel Measure for Disease Severity of Multiple Sclerosis Using Real-World Data

Authors: Amy L Phillips, 1 Michael A Munsell, 2 Joseph Menzin2

¹EMD Serono Inc., Rockland, MA, USA;

²Boston Health Economics, Inc., Waltham, MA, USA

Email Address for Correspondence: Amy.Phillips@emdserono.com

Objective: To test and validate a new predictive model for disease severity of multiple sclerosis (MS) for use in retrospective claims database analyses.

Methods: A negative binomial regression was estimated to predict annual all-cause medical costs among patients with MS using retrospective healthcare claims data from the IMS PharMetrics Plus database (January 2006–June 2013). Coefficients reaching statistical significance (p<0.05) and increasing costs by ≥5% were selected for inclusion in a MS-specific severity score (scale of 0–100). Components of the score included rehabilitation services, altered mental state, pain, disability, stiffness, balance disorder, urinary incontinence, numbness, malaise/fatigue, and infections. The original regression was reevaluated using the MS-specific severity score as a covariate, and then tested by comparing each patient's predicted versus actual costs. Model bias was further evaluated by MS score tertile, representing low, medium, and high MS severity. The predictive model was derived using 50% of a random sample and tested/validated using the remaining 50%.

Results: Overall (ie, without stratification by severity), the average predicted annual all-cause medical cost was \$11,134 for the original model sample (n=11,385; vs \$10,528 actual) and \$11,303 for the validation sample (vs \$10,620 actual). The model had consistent bias (approximately \$600 or 6% of actual costs) for both the original and validation sample. In the validation sample, the mean severity score was 0.24, 8.95, and 21.77 for the low, medium, and high MS severity tertiles, respectively. On average, the model predicted mean costs most accurately among patients with lower disease severity (\$5,243 predicted vs \$5,233 actual cost for lowest tertile).

Conclusions: This MS severity score model was able to predict annual all-cause medical costs with acceptable estimations and its performance is in line with other published validated models.

Disclosures or potential conflicts of interest [not included in character count]: Study supported by EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany) and Pfizer Inc, New York, NY, USA. ALP is an employee of EMD Serono, Inc., Rockland, MA, USA (a subsidiary of Merck KGaA, Darmstadt, Germany). MAM and JM are employees of Boston Health Economics, Inc., which receives funding from EMD Serono, Inc.

#10: The 2015 US Payor Landscape for Specialty Pharmacy: Results from a Survey of Medical and Pharmacy Directors

Authors: Richard A Brook; 1,2 Michael J. Sax; 3, James (Jim) E Smeeding 1,4

¹TPG-National Payor Roundtable, Glastonbury, CT

²The JeSTARx Group, Newfoundland, NJ

³The Pharmacy Group; Glastonbury, CT

⁴The JeSTARx Group, Dallas, Tx

Email Address for Correspondence: Rich.Brook@TPG-NPRT.com

Objective: Determine how medical and pharmacy directors [MDs+PDs] of US health plans, insurers, and PBMs manage specialty pharmaceuticals (SPs).

Methods: Managed care [MC] MDs+PDs completed an online interactive survey on: advisor+plan information; use of specialty pharmacies, and current/future coverage of SPs.

Results: Fifty-four percent of respondents were MDs, the remainder mostly pharmacists. Most worked for a health plan (83.6%). Plans were 39.6%=local; 35.4%=national; 25.0%=regional and could cover multiple types of members and 91.3% covered commercial lives, 89.1% Medicaid; 91.3% Medicare MA-PDP and 76.1% Medicare PDP-only lives. SP providers were restricted by 53.7% of the plans. The majority of plans restrict the SP provider services to a small set under contract (63.0%), 17.4% allowed any SP; and 6.5% only restricted products available through multiple specialty pharmacies. Plans covered clinicianadministered products (injections/infusions) under the: medical-benefit (MB=67.3%); none exclusively under the pharmacy-benefit (PB-0%);] and 32.7% using a cost-thresholds; Most plans (72.9%) do not anticipate a change, 18.8% expect a change before 12-2016 and 2.1% before 12-2018. Oral Biologics (OBs) were managed under the PB 78.3%; the MB (10.9%): and based on cost-thresholds (10.9%). Benefits for OBs are not expected to change by 71.1% of the plans, 11.1% were currently making changes; 13.3% expect changes before 12-2016; and 4.4% before 12-2018. SP and OB co-pays vary based on the group/benefit design, and are shifting from fixed to percent co-pays. Responses to open ended questions placed SP products at the top causes for concern currently, and for the coming years.

Conclusions: Expenditures for SP products and the use of specialty pharmacy will continue to grow. The environment for MC is undergoing a series of changes, and payor MDs+PDs, who commonly serve as P&T Committee members, have distinct opinions as to how to alter the process to adapt to these influences.

Disclosures: None

#11: Walgreens Local Specialty Pharmacies provide Convenient Access to Oral Chemotherapies for Patients throughout the United States

Authors: Francis Staskon, PhD¹; Nicole Leiter, PharmD¹; Heather Kirkham, PhD, MPH¹ Walgreens, Deerfield, IL

Email Address for Correspondence: heather.kirkham@walgreens.com

OBJECTIVE: To identify utilization trends and access to oral oncolytics for patients using Walgreens Local Specialty Pharmacies (LSP).

METHODS: This retrospective cohort study used pharmacy claims to identify patients who were either new to pharmacy/therapy based on a 6-month preview of patients utilizing oncolytics from September 2013.

RESULTS: Between March 2014 and March 2015, 8,127 patients were identified as taking at least one of 30 oral oncolytics, of which 21 were designated as limited distribution (LDD). Patients received 28,834 fills, with an average AWP cost of \$8,894. Of these 8,127 patients, just over half were males (52.8%), resided in the Midwest (44.3%) or Southern (31.3%) regions, and were over 60 (mean age=64 years; median age=66 years). Most patients were covered with a commercial plan (90.7%) or with Medicaid coverage (9.3%). The majority of patients (64%) had a prescribed LDD for their treatment. Within the LSP network, community pharmacies dispensed 56% of oncolytic fills, pharmacies near hospital systems dispensed 32.3% of fills, and 11.7% of fills were dispensed from a pharmacies in medical office buildings.

CONCLUSIONS: Walgreens Local Specialty Pharmacies allow access to both LDD and non-LDD oral chemotherapies in retail pharmacy settings for cancer patients throughout the United States.

Disclosures: All authors are currently employed by the study sponsor, Walgreen Co.



#12: Quality of Life, Depression, Anxiety, and Medication Adherence among Patients with Cystic Fibrosis using Pharmacy Management Services

Authors: Heather Kirkham, PhD, MPH¹; Francis Staskon, PhD¹; Nishita Hira, PharmD²; Darren McLane, PharmD²

¹Walgreens, Deerfield, IL; ²Walgreens, Carnegie, PA

Email Address for Correspondence: heather.kirkham@walgreens.com

OBJECTIVE: To assess the relationship of quality of life (QOL), depression, and anxiety on medication adherence among patients with cystic fibrosis who participated in a pharmacy management program.

METHODS: This 2-year, observational study used three, validated patient reported outcomes (PROs) instruments. QOL was measured via the parent, child, and teen/adult versions of the CFQ-R, and depression and anxiety were measured via the adult, pediatric, and parent proxy versions of the NIH PROMIS® Depression and Anxiety Short Forms, respectively. Upon enrollment in the pharmacy management program, patients (or parents of patients) were emailed an invitation to consent to be in the study and asked to complete a HIPAA-compliant, web-based survey (English/Spanish) every 6 months for 2 years. Medication adherence was measured using 6-month composite medication possession ratio (cMPR) for three CF medications (inhaled tobramycin, inhaled aztreonam, and dornase alfa) based on administrative pharmacy claims.

INTERIM RESULTS: As of August 2015, 132 participants had completed at least one survey and had filled at least one CF prescription. Fifty-five percent of participants were female; the mean age was 34.5 years (SD=12.6); and the mean number of drug classes was 1.7 (SD=0.8). Having at least 60 days in the program (odds ratio [OR]=2.9, 95% CI [1.3, 6.6]), and not scoring above the national average for CFQ-R physical functioning at baseline (3.9, [1.1, 13.7]), were associated with a greater likelihood of being adherent (cMPR□80%), while controlling for age, gender, the number of CF medications, anxiety, and depression.

CONCLUSIONS: Patients with CF appear to benefit from structured pharmacy-led patient management programs designed to facilitate optimal management of their medications, adherence barriers, and related comorbidities. Additional follow-up should assist future research to identify the program components that are most effective at improving medication adherence over time.

Disclosures: All authors are currently employed by the study sponsor, Walgreen Co.



#13: Descriptive Study of Patients on Infertility Treatments using Walgreens Pharmacies

Authors: Julia Zhu, MPH¹; Kajaal Patel, RPh²; Ann Scalia, RN, BSN, CNOR²; Rick Miller, BS, MBA²; and Heather Kirkham, PhD, MPH¹

¹Walgreens, Deerfield, IL; ²Walgreens, Carnegie, PA

Email Address for Correspondence: heather.kirkham@walgreens.com

OBJECTIVE: To describe the age characteristics of patients on infertility medications through all Walgreens Pharmacy channels (specialty and retail).

METHODS: This retrospective cohort study used pharmacy claims to identify patients who received at least one infertility medication between January 2014 and June 2015.

RESULTS: Of the patients using Walgreens infertility services, 23% of patients were aged 29 years or younger; 31% were aged 30 to 34 years; 24% were aged 35 to 39 years; 12% were aged 40 to 44 years; and 8.4% were aged 45 years or older. The mean age was 34.8 years old (SD=7.8). The majority of patients were using either clomiphene (63.5%) or injectable gonadotropin (6.0%). The mean age of patients using clomiphene (M=34.9 ± 8.4 years, N=37,537) was significantly younger than those using injectable gonadotropin (35.3±5.3 years; 3,527; p<.001).

CONCLUSIONS: Even with the trend in delayed child-bearing among Americans, over half of patients using Walgreens infertility services was under 35 years of age (55%). Our finding that gonadotropin users were older than clomiphene users is consistent with clomiphene's indication as a first-line therapy.

Disclosures: All authors are currently employed by the study sponsor, Walgreen Co.

#14: The Effect of a Multidisciplinary Healthcare Team on Patient Outcomes in Patients Receiving Chemoradiation for Head and Neck Cancers

Author: Shannon Gowen¹

¹NYS Center of Excellence in Bioinformatics and Life Sciences

Email Address for Correspondence: sgowen@buffalo.edu

Objective: The aim of this study is to assess the effect of collaboration between members of a multidisciplinary healthcare team, including physicians, nurses, pharmacists, and a dietician, on patient outcomes and healthcare costs in patients with head and neck cancers receiving concurrent radiation and chemotherapy.

Methods: This study is prospective in design and includes patients who are receiving chemotherapy and radiation treatment in an outpatient oncology setting. All new patients have an initial consultation with a dietician within one week of their first treatment, and further interactions occur as deemed appropriate based on each patient's needs. Patient-specific information regarding side effects from treatment is collected via questionnaires that are administered by a nurse or pharmacist semiweekly. From these completed questionnaires, the pharmacist identifies whether any pharmacologic or dietary interventions need to take place, with a follow-up recommendations to the patient's physician or referral to the dietician. Patients will be followed for 6 months post-treatment.

Results: This study was initiated in August of 2015. Six patients are currently included; four of the six patients are nearing the end of their treatment, and each had already experienced unintentional weight loss ranging from 10 pounds to 63 pounds. Three patients rate their mouth pain as severe, and four patients indicate that the pain interferes with their ability to eat and drink.

Conclusions: Patients receiving chemoradiation for head and neck cancers experience significant oral pain and unintentional weight loss. More needs to be done to alleviate these adverse outcomes, and the addition of a pharmacist and dietician to the healthcare team may improve pain control and prevent significant weight loss, resulting in improved patient outcomes and quality of life.

Disclosures: None-provided



#15: Retrospective analysis of the medication utilization and clinical outcomes of patients treated with various regimens for hepatitis C infection.

Authors: William D. Trombatt, PharmD^{1,2}, Pamela H. Koerner, BS, PharmD, BCPS¹, Zoie N. Craft, BA², Richard T. Miller, RPh, MBA, CSP², Khalid M. Kamal, MPharm, PhD¹

¹Duquesne University Mylan School of Pharmacy;

Email Address for Correspondence: koerner@duq.edu

Objective: To evaluate medication utilization and clinical outcomes (SVR, side effects, adherence rates, reasons for discontinuation, etc.) of patients being treated for HCV with any approved combination of ribavirin, interferon products, simeprevir, and sofosbuvir.

Methods: The records of patients receiving their HCV medications through Walgreens Specialty Pharmacy who started therapy for HCV and were eligible for SVR between January 1, 2014 and December 31, 2014 were retrospectively reviewed. Data was collected from Walgreens prescription processing and clinical assessment software. Patient responses in assessments were obtained and evaluated through Excel and SPSS software using descriptive statistics.

Results: Of the 389 patients analyzed, 79.7% were between 46 and 65 years of age. The most common genotypes were genotype 1 (68.4%) and genotype 2 (16.2%). 44.0% of patients were treatment naïve and 33.9% had received previous treatment for HCV. The treatment history for 22.1% of patients was unknown. SVR rates were higher or equal in all but one subgroup for treatment naïve patients compared to treatment experienced patients.

Out of the original 947 patients identified, discontinuation of treatment occurred in 51 patients. The data showed that the two largest reasons for discontinuation were adverse events (13 patients) and financial reasons (9 patients). Nine of the 13 patients who discontinued therapy due to adverse events were on a regimen containing peginterferon.

Conclusion: SVR rates are higher for patients using a sofosbuvir containing regimen than they were for ribavirin plus peginterferon alfa with or without a protease inhibitor. Also, SVR rates observed in clinical trials are similar to what is being seen in real-world data. In addition to SVR rates, the adverse event profile of these medications is much more tolerable and discontinuations are lower than with previous therapies.

Disclosures: There are no potential or actual financial conflicts of interest with any of the authors.

²Walgreens Co.



#16: In Early RA SWEFOT Patients with Non-Response to Methotrexate Monotherapy the Change in Multibiomarker Disease Activity Score is Differentially Associated With Subsequent Response to Non-Biological Versus Biological Therapy

Authors: Karen Hambardzumyan¹; *Rebecca Bolce²; Saedis Saevarsdottir³; Kristina Forslind⁴; Ingemar F. Petersson⁴; Pierre Geborek⁴; Sofia Ernestam⁵; Eric H. Sasso²; David Chernoff²: Scott E. Cruickshank⁶: Ronald F. Van Vollenhoven¹

¹Unit for Clinical Therapy Research, Inflammatory Diseases, KAROLINSKA INSTITUTE, Stockholm, Sweden, ²Crescendo Bioscience, South San Francisco, United States,

Email Address for Correspondence: rbolce@crescendobio.com

Objective: Evaluate change in multi-biomarker disease activity score (Δ MBDA) during methotrexate (MTX) monotherapy as a response predictor for subsequent triple versus biological therapy.

Methods: Swedish Farmacotherapy (SWEFOT) trial patients with early rheumatoid arthritis (eRA) and DAS28 >3.2 received MTX monotherapy for 3 months. Non-responders (DAS28>3.2) at month 3 were randomized to non-biological triple disease modifying antirheumatic drugs (DMARDs) (Arm A) or anti-TNF (infliximab) with MTX (Arm B). Non-responders (n=129) at Month 3 (Arm A, n=62; Arm B, n=67) were analyzed by MBDA at baseline (BL) and Month 3. MBDA decreases from BL to Month 3 were grouped by tertiles: small (≤6), moderate (7-20) or large (>20). To assess Month 3 ΔMBDA as a response predictor for triple or anti-TNF therapy at Year 1, small/moderate MBDA decreases were compared to large decreases for Arms A and B. The proportion of patients in Arm A versus B with Year-1 response was evaluated by the odds ratio (OR) for patients with small/moderate versus large decreases. OR homogeneity between both cohorts was assessed by Breslow-Day test.

Results: Among Month 3 clinical non-responders with large decreases in MBDA from BL to Month 3, 67% responded to triple therapy and 37% to anti-TNF treatment (OR=3.33) at year 1' among those with small/moderate MBDA decreases during MTX monotherapy, 43% responded to triple therapy and 57% responded to anti-TNF (OR=0.577). The relative treatment effect of Arm A versus B differed according to Δ MBDA from BL to 3 months (p=0.032).

Conclusions: Among eRA patients unable to achieve low disease activity on MTX monotherapy, those with the greatest MBDA decreases were likely to respond to triple therapy whereas patients with lesser MBDA decreases were likely to respond to anti-TNFs. These findings suggest that in MTX non-responders, ΔMBDA may help guide subsequent therapy and increase effectiveness.

Disclosure of Interest: K. Hambardzumyan: None declared; R. Bolce Shareholder of: Myriad Genetics Inc. Employee of: Crescendo Bioscience; S. Saevarsdottir: None declared; K. Forslind: None declared; I. Petersson Speakers bureau: UCB Pharma, Pfizer, AbbVie; P. Geborek: None declared; S. Ernestam: None declared; E. Sasso Shareholder of: Myriad Genetics, Inc. Employee of: Crescendo Bioscience; D. Chernoff Consultant for: Crescendo Bioscience; S. Cruickshank Consultant for: Crescendo Bioscience; R. Van Vollenhoven Grant/research support:Abb Vie, BMS, GSK, Pfizer, Roche, UCB Consultant for: AbbVie, Biotest, BMS, Crescendo Bioscience, GSK, Janssen, Lilly, Merck, Pfizer, Roche, UCB, Vertex.

³Department of Medicine, KAROLINSKA INSTITUTE, Stockholm,

⁴Institution of Clinical Sciences, Section of Rheumatology, Lund University Hospital, Lund,

⁵Institution LIME Medical Management Centre, KAROLINSKA INSTITUTE, Stockholm, Sweden,

⁶Scott Cruickshank and Associates, Santa Barbara, United States



#17: Recent Cost Trends in Patients Using Biologic Therapies for the Treatment of Psoriasis

Authors: Andreas Kuznik¹; Sergio Eslava²; John Cai²

¹Celgene Corporation, Warren, NJ; ²Celgene Corporation, Summit, NJ

Email Address for Correspondence: akuznik@celgene.com

Objective: This analysis determines the change in healthcare costs for patients with psoriasis, an immune-mediated systemic inflammatory disease, to managed care organizations. The therapeutic classes available to treat psoriasis include biologic drugs. Despite rising wholesale acquisition costs of biologics in recent years, little documented evidence is available on cost trends from the US managed care perspective.

Methods: Continuously enrolled adult patients with ≥2 outpatient diagnoses for psoriasis (ICD-9: 696.1) were selected from the MarketScan Commercial and Medicare Supplemental databases if their first biologic prescription date (index date) occurred July 2008 through July 2013 and they were biologic-naive ≥6 months pre-index. Healthcare costs were based on annual reimbursements for 6 patient cohorts initiating biologic therapy from 2008 to 2013. Results were stratified by all-cause vs. psoriasis-related costs and further subdivided into medical inpatient, medical outpatient, emergency room, and pharmacy costs.

Results: 13,045 patients met the inclusion criteria and composed the 6 cohorts. All-cause annual healthcare costs for the years 2008-2013 were \$27,973, \$31,507, \$35,006, \$38,533, \$42,289, and \$43,431, showing increases of 55.3% overall and averaging 11.1% or \$3,092 annually. Respective psoriasis-related estimated annual costs were \$19,991, \$21,976, \$25,059, \$27,853, \$31,575, and \$32,739, showing increases of 63.8% overall and averaging 12.8% or \$2,550 annually. Although costs increased over time in all categories assessed, the major driver of this trend was psoriasis-related pharmacy costs, predominantly the cost of biologic therapies. These costs were estimated for the years 2008-2013 at \$15,871, \$18,032, \$21,403, \$22,880, \$27,899, and \$29,240, showing increases of 84.2% overall and averaging 16.8% or \$2,674 annually.

Conclusions: For US managed care payers, total healthcare cost incurred for patients initiated on biologic therapy for psoriasis has increased substantially in recent years, primarily driven by changes in psoriasis-related pharmacy costs.

Disclosures: Andreas Kuznik, Sergio Eslava, and John Cai are employees of Celgene Corporation.