Section Advisory Group on Outcomes and Value
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Sample Multiple Sclerosis (MS) Clinical Outcomes Dashboard for a Specialty Pharmacy Program

This document is intended to provide a reference for potential clinical outcomes that can be used to monitor the safety and efficacy of the pharmacists and patient management program within a health system specialty pharmacy program. It is not intended to serve as an all-inclusive list and not all metrics may be required for a specific organization. No benchmarks are recommended due to lack of available data. Organizations should consider evaluating metrics overtime or at a frequency determined based on their needs.

Metric	Description
Disease State Specific	
Vitamin D	**Goal**: ensure patients have a vitamin D level, are adequately treated, and achieve adequate levels Potential outcomes: • Percent of patients with a vitamin D level at baseline • Percent of patients with abnormal vitamin D levels at baseline • Percent of patients receiving treatment for a low vitamin D level • Percent of patients achieving adequate vitamin D levels after a certain duration • Change in vitamin D level after certain duration of treatment
Safety	
Safety parameters evaluated	**Goal:** evaluate and address relevant safety precautions prior to treatment initiation and periodically thereafter Potential outcomes: • Percent of patients with relevant safety parameters evaluated and addressed prior to starting therapy • Percent of patients not initially meeting safety parameters and requiring intervention prior to starting therapy • Percent of patients not meeting safety parameters and requiring intervention while on therapy *See appendix for specific parameters*
Efficacy	
Relapse rate	**Goal:** identity patients with poor response to therapy as evidenced by relapse(s) Potential outcomes: • Relapse rate (in overall population): # (include duration of time assessed over, e.g. rate per 6 months at 1 year after starting therapy) • Percent of patients with a relapse since starting therapy, last assessment or medication titration • Mean and/or median change in relapse rate # (include duration: last year, since last assessment, since starting therapy, since medication titration – if using a duration that does not include a time duration (such as since last assessment) recommend adding the actual duration of time the rate of relapse is representing) • Percent of patients with stable or decrease in relapse rate since starting therapy, last assessment, or medication titration *See appendix for details on definition of relapse rate*

Patient reported response to therapy	**Goal:** assess patient perception of response to therapy Potential outcomes: • Percent of patients w/o a response where pharmacist intervened • Percent of patients w/o a response educated on treatment expectations • Percent of patients with no change in disease manifestation • Percent of patients reporting adequate management of MS symptoms • Percent of patients reporting stable MS symptoms • Percent of patients reporting better or stable condition *See appendix for example assessment questions*
Symptom control	**Goal:** evaluate symptoms and optimize symptom control Potential outcomes: • Percent of patients with stable, improved, worsened, and resolved symptoms overall and/or for specific symptoms • Percent of patients with stable, improved or resolved symptoms since starting therapy, last assessment, or medication titration • Percent of patients with worsening symptoms where pharmacist intervened *See appendix for example assessment questions*
Patient reported fatigue	**Goal:** manage and optimize patient fatigue Potential outcomes: • Percent of patients with stable, improved, worsened, and resolved fatigue • Percent of patients with stable, improved or resolved fatigue since starting therapy, last assessment, or medication titration • Percent of patients with worsening fatigue where pharmacist intervened *See appendix for assessment questions*
Gait improvement	**Goal:** evaluate gait and disability Potential outcomes: • Patients meeting criteria and initiated on dalfampridine therapy • Change in 25-foot walk test results (including duration of time e.g. baseline to 3 months, 1 year etc.) • Percent of patients with improved or stable gait • Percent of patients with stable, improved, and worsened disability *See appendix for additional assessments*
Utilization	
Urgent Care, ER, hospitalization or unplanned clinic visit related to MS	**Goal:** decrease utilization Potential outcomes: • Rate of urgent care, ER, hospital and/or unplanned clinic visits related to MS (include duration of time assessed over, e.g. rate per 6 months at 1 year after starting therapy) • Percent of patients with a visit related to MS since starting therapy • Rate of visit(s) related to MS in the last 12 weeks *See appendix for details*
Quality of Life	
Patient reported quality of life assessment	Goal: improve patient report quality of life Potential outcomes: • Percent of patients reporting an improvement in QOL assessment since starting therapy (include time since starting therapy) • Percent of patients with a decrease in missed ADL due to disease state *See appendix for detailed assessment options*

Work assessment (for employed patients only)	Goal: evaluate and optimize impact of disease on work Potential outcomes: • Percent of patients missing work because of their condition and average # of hours for those that missed work • Average patient reported impact of condition on productivity at work: 0-10 (0 = no effect, 10 = completely preventing them from working)
Adverse Effects	

Adverse effects and plan	Goal: mitigate side effects or change therapies to improve adherence and efficacy
	Potential outcomes:
	• Number per patient/Percent of patients with clinically significant adverse effect (AE) reported (i.e. minor and/or major AEs)
	  ○ Minor: general/common adverse effects
	  ○ Major: death, life-threatening AE, hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect
	• Number/percent of patients with adverse effect that required the pharmacist to develop a mitigation strategy
	• Description of AE mitigation plan (e.g., non-pharmacologic recommendations, supportive therapy, dose reduced, discontinued therapy/therapy change)

Drug Interactions	
Drug interactions	Goal: identify and mitigate drug interactions Potential outcomes: • Number per patient/Percent of patients with a clinically significant drug interaction identified (i.e. drug-drug interactions, drug-disease interactions, drug-lab interactions, interactions requiring monitoring and/or dosage adjustments or requiring change to current agent) • Number/type of interventions pharmacists made to mitigate drug interaction (no change/patient counseled, discontinue medication, dose change, medication change) include impact of intervention? (e.g. prevented serious AE, prevented potential treatment failure) • Of interventions identified – how many accepted recommendations by prescriber team?
Adherence	
Missed doses	Goal: identify, manage and improve patient adherence Potential outcomes: • Percent of patients with a missed dose • Average (range) number of missed doses per a specific time frame for patients that missed a dose • Number of patients with each reason or and intervention to impact nonadherence (e.g. adverse effect identified and treated, cost challenge solved, etc.) • Percent of patients with a PDC >90%, may consider utilizing average/adjusted PDC • Consider other patient-reported outcomes

Appendix

Safety parameter details	Parameters for each drug or references
Definition of relapse rate	• How to define relapse (true vs pseudo relapse) rate (patient reported vs. from certain factors in the medical record (if so what is included) etc. This could be a new/reactivated lesion or clinical/subjective report of new s/sx of recurrence. References to consider when evaluating specific clinical criteria qualifying as relapse: -Galea I, Ward-Abel N, Heesen C. Relapse in multiple sclerosis. *BMJ* 2015; 350 :h1765. -McGinley MP, Goldschmidt CH, et al. Diagnosis and Treatment of Multiple Sclerosis: A review. *JAMA*. 2021;325(8):765-779.
Patient reported response to therapy assessment options	• Percent of patients with no change in disease manifestation (based on answering "no change" to the following question - how would you describe you MS since we last spoke with you: no change / symptoms worsened / relapse occurred) • Percent of patients reporting adequate management of MS symptoms (based on answering yes to "Are your MS symptoms managed adequately? yes / no) • How would you describe your MS since starting therapy: stable / worsened / critical / NA – new start • In regard to your condition, how are you feeling compared to the last time we spoke? better / no change / worse • Percent of patients making progress towards achieving therapeutic goal or documentation of appropriate reason for not making progress (e.g. too soon to tell)
Patient reported symptom assessment options	• Patient response change in MS symptoms: new onset / stable / improved / resolved / worsened • Specific patient reported symptoms: weakness/fatigue, tremor/ataxis, nystagmus/trouble speaking/swallowing, sensation, urinary or bowel dysfunction, visual disturbances, mood alteration / dementia – include an option to evaluate these (beyond listing the symptom) ○ Examples : severity of muscle spasticity or weakness: scale of 0-10 (0 = no spasticity/weakness, 10 = worst spasticity/weakness) and for fatigue (see validated assessments below) • Group discussed adding a list of the most common symptoms categorized by frequency (high/medium/low etc.) • Consider utilization of symptom MS checker
Patient reported fatigue	• Consider adding validated assessments such as The Multiple Sclerosis Fatigue Self-Efficacy Scale, PROMIS SF and Fatigue Severity Scale and the Modified Fatigue Impact Scale
Gait improvement	• Disability PDDS (patient determined disease steps) may be considered
Utilization details	• Recommend collecting information for each visit type separately and presenting data both separately and combined.
Patient reported quality of life assessment options	• Consider using Delay in Disability Assessment • How have you felt since starting therapy: 9-10 excellent, 7-8 very good, 5-6 good, 3-4 fair, 1-2 poor • Average patient reported rating of how their condition affects their abilities to do regular activities other than work: 0-10 (0 = no effect, 10 = completely prevented from daily activities) • Average patient reported rating of how their doing considering all the ways their condition affects them: 0-10 (0 = very well, 10 = very poor) • Have you missed work, school, or are you unable to perform normal activities of daily living due to your disease state? Yes / no • Have you experienced any of the following in the past 4 weeks due to your disease? Missed days from work, school, or planned activities? Yes / no • If yes, how many of each: #