## 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.

<table>
<thead>
<tr>
<th>Metric</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Disease State Specific</strong></td>
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| 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** | **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** | **Goal:** improve patient reported 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 | 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) |
| Adverse effects and plan |--------------------------------------------------------------------------------|
| 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? |
| Drug interactions |--------------------------------------------------------------------------------|
| Adherence | 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 |
| Missed doses |--------------------------------------------------------------------------------|
### 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:

### 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/touble 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: #