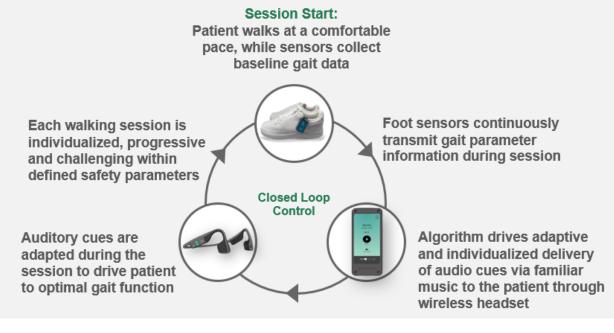
A Budget Impact Model to Evaluate the Budget Impact of Treating Walking Impairment in Chronic Stroke, a US Perspective

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Background

- Stroke is the second-leading cause of death and thirdleading cause of adult disability in the United States (US).¹
- Nearly half of patients with chronic stroke (≥ 6 months poststroke) have walking impairment, which is associated with high healthcare resource utilization (HCRU) costs.²
- Slower walking speeds can reduce independence and mobility outside of the home, as well as increase cognitive decline and risk of falls.³
- Without the ability to walk at least 0.8 m/s, the threshold for community ambulation, many stroke survivors cannot safely navigate their communities (or are unable to independently leave their homes).³
- There is an unmet need for an effective rehabilitation method for patients with chronic stroke walking impairment.⁴
- Clinical practice guidelines recommend physical activity, physical therapy, and rhythmic auditory stimulation (RAS) for the long-term rehabilitation of individuals post-stroke.⁵⁻⁷
- Despite clinical guidelines, there are functional, social, and perceptual barriers to participating in such activities⁷⁻⁹ and survivors of stroke spend 78% of their waking hours sedentarily.¹⁰
- RAS is a form of neurologic music therapy that utilizes auditory motor entrainment in the rehabilitation of movements that are naturally rhythmic (such as walking).¹¹ Although decades of research support the effectiveness of RAS, this intervention is traditionally administered by Neurologic Music Therapists (NMTs);¹² with less than 1,000 credentialed NMTs in the US,¹³ patient accessibility to RAS is limited.
- MR-001 is an investigational prescription neurorehabilitation system intended to improve walking and ambulation status in adults with chronic stroke.
- MR-001 delivers an intervention based on the principles of RAS for use at home and/or in the community environment.

Figure 1: MR-001 session overview



Objective

• To estimate the budget impact, from a US payer perspective, associated with the reimbursement of MR-001 for the treatment of chronic stroke walking impairment.

Methods

- A budget impact model (BIM) was developed using Microsoft Excel[®] following the International Society f Pharmacoeconomics and Outcomes Research (ISP) best practice guidelines.¹⁴
- The patient population included adults aged \geq 18 years with chronic stroke walking impairment.
- Interventions captured in this analysis were 'MR-00' min walking sessions with MR-001, 3x per week for 2 months), 'No Treatment' (no treatment for walking impairment), 'Therapeutic Exercise' (30 min walking sessions, 3x per week for 2 months), and 'Physical Therapy' (24 physical therapy sessions per year rela to walking rehabilitation).
- All patients were assumed to fully adhere to their prescribed interventions (i.e., 100% adherence).

Figure 2: Budget impact model structure



Table 2: Intervention-specific reference case parameters and input values

Parameter	MR-001	No Treatment	Therapeutic Exercise	Physical Therapy
Patient Shares: Current Scenario ²⁰	0%	56%	8%	36%
Patient Shares: Future Scenario ²⁰	5%	51%	8%	36%
Intervention price	~\$1,500.00 ²⁰	\$0.00	\$0.00	\$75.00 ²¹⁻²⁴
	(monthly rental)	φ0.00		(per 30-minute session)
Intervention frequency (per year)	2 rental periods	N/A	24 sessions ²⁵	24 sessions ^{6,26-27}
Patient co-pay	20% ²⁸	N/A	N/A	22%*
Reimbursement amount	\$1,160.00 ⁺	N/A	N/A	\$58.18 ²⁹
Walking speed increase	0.14 m/s ²⁵	0.00 m/s	0.06 m/s ²⁵	0.07 m/s ³⁰
Patients converted to community ambulators	47.5% ²⁵	0.00%	25.0% ²⁵	25.0%‡

*Calculated percentage equal to the remaining cost after the reimbursement amount (associated with HCPCS code 97110)²⁹ is deducted from the intervention price. [†]Calculated remaining cost after the patient co-pay is deducted from the intervention price. [‡]Assumed equivalent to Therapeutic Exercise.



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References

Abbreviations BIM = budget impact model; HCRU = healthcare resource utilization; ISPOR = International Society for Pharmacoeconomics and Outcomes Research; LTC = long-term care; m/s = meter per second; NMT = neurologic music therapist; N/A = not applicable; PIMPM = per-indicated-member per-month; PMPM = per-member per-month; RAS = rhythmic auditory stimulation; US = United States.

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for POR)	Parameter	Value
	Time horizon	1 year
ears	Plan size	1,000,000
	Annual incidence of chronic stroke in the US	0.20%*
1' (30 `2	Prevalence of chronic stroke in the US	3.2% ¹⁷
9	Proportion of survivors of stroke with chronic walking impairment	50% ²
ated	Mean annual post-stroke healthcare costs	\$11,214.66 ^{§1} 8
	Healthcare resource utilization cost reduction per every 0.10 m/s increase in walking speed	\$2,026.89 ^{§19}
	*Calculated using the annual stroke incidence rate ¹⁵ and stroke mortal	lity rate.16

Table 1: Reference case parameters and input values

§Values have been inflated to 2023 US Dollars.

Results

- Reimbursing MR-001 for chronic stroke walking rehabilitation was associated with costsavings for the payer of \$439,954 over a one-year time horizon (**Table 3**).
- For patients treated with MR-001, the intervention cost was offset by the associated reduction in HCRU driven by improvement in walking speed (Table 3).
- Compared to the current scenario, an additional 2.4% of patients were expected to become community ambulators after the introduction, and subsequent uptake, of MR-001 (**Table 3**).
- Total HCRU costs per patient were lowest for MR-001 relative to the comparators in the analysis (Table 4).
- The robustness of model results were supported by multiple sensitivity analyses that also demonstrated cost savings to the public payer (**Table 5**).

Table 3: Reference case economic and patient outcomes for year one

Outcome	Current Scenario (without MR-001)	Future Scenario (with MR-001)	
Total budget impact for payers	\$188,840,694	\$188,400,739	
Total costs PMPM	\$15.74	\$15.70	
Total costs PIMPM	\$925.77	\$923.62	
Patients converted to community ambulators	11.0%	13.4%	

Translates to an additional 404 individuals becoming community ambulators with the introduction of MR-001. In the reference case, 404 of the 850 patients treated with MR-001 were converted to community ambulators; as such, these patients would theoretically gain the ability to independently leave their homes and successfully navigate their communities.

Discussion

- resulting in the greatest reduction in HCRU costs for this treatment group.

Conclusions

- There are significant clinical, humanistic, and economic burdens associated with walking impairment for patients with chronic stroke.
- stroke



ncrementa

-\$439,954

-\$0.04

-\$2.16

2.4%*

Table 4: Reference case economic outcomes to the payer by intervention for year one

Outcome	MR-001	No Treatment	Therapeutic Exercise	Physical Therapy
Intervention cost per patient	\$2,320.00	\$0.00	\$0.00	\$1,396.32
Total HCRU cost per patient*	\$8,377.02	\$11,214.66	\$9,998.53	\$9,795.84
*Total HCRU cost per patient includes the annual HCRU cost to treat patients with chronic stroke minus the reduction in the annual HCRU cost				e annual HCRU cost

associated with an increase in walking speed

Table 5: Results of sensitivity analyses

Analysis	Intervention Costs (to payer)	HCRU Costs (to payer)	Total Costs (to payer)
Reference case	\$1,971,824	-\$2,411,778	-\$439,954
Include recurrent stroke hospitalization costs and LTC costs*	\$1,971,824	-\$3,380,871	-\$1,409,048
Increase HCRU reduction per 0.10 m/s increase in walking speed to \$2,432.27 [†]	\$1,971,824	-\$2,894,143	-\$922,319
Decrease HCRU reduction per 0.10 m/s increase in walking speed to \$1,621.51 [†]	\$1,971,824	-\$1,929,425	\$42,399
Increase patient shares for MR-001 to 10%	\$3,943,648	-\$4,823,556	-\$879,909
Decrease patient shares for MR-001 to 2.5%	\$985,912	-\$1,205,889	-\$219,977
Increase proportion of patients with chronic stroke and walking impairment to 70%	\$2,760,554	-\$3,376,490	-\$615,936
Decrease proportion of patients with chronic stroke and walking impairment to 30%	\$1,183,094	-\$1,447,067	-\$263,973

Recurrent stroke hospitalization costs = \$15,268.62³¹; annual LTC costs = \$113,800.94³². Values have been inflated to 2023 US Dollars. [†]This parameter was varied by $\pm 20\%$ to reflect uncertainty in its value.

• Improvement in walking speed was observed for Physical Therapy, Therapeutic Exercise, and MR-001. Patients achieved a greater increase in walking speed using MR-001 than other comparators,

• Strengths: Model was developed following ISPOR best practice guidelines and eligible patient population was highly representative of the patient population indicated for treatment with MR-001.

• Limitations: MR-001 assumptions were based on clinical trial data not real-world use, patient share distributions might not reflect actual uptake patterns (Table 2), HCRU cost reduction related to walking speed was based on non-stroke population data (Table 1), combination therapies were not included, and treatment adherence rates were assumed to be 100% for all interventions.

• Results from this budget impact analysis suggest that US payers should consider reimbursing MR-001 as a cost-saving intervention to improve walking and ambulation status in patients with chronic

