PATIENT NAME:_____

OBI, MEDICAL DEVICE NEEDS ASSESSMENT (DNA)©

Purpose: This form is intended to document the Obi Robot trial assessment results for a specific patient, including information relating to medical necessity.

Instruction: Complete STEPS 1,2 and 3 in order. Form begins on pg.2.

CAUTION: This form contains sensitive personally identifiable information(PII)/protected health information (PHI). It is the responsibility of the user (person/organization in possession) to: 1. Only use this form and disclosure of its PII/PHI for reasons pertaining to its purpose. 2. Use appropriate physical, technical and administrative safeguards to prevent use or disclosure of PII/PHI other than as necessary.

STEP3, FINAL DETERMINATION, SUMMARY

☐

ALL STATE PROVISIONS OF MEDICAL NECESSITY ARE MET.
Reference:

ALL LOWER COST ALTERNATIVES WERE FOUND TO BE UNSUCCESSFUL.

THE PATIENT CONTINUOUSLY DEMONSTRATED SAFE AND EFFECTIVE USE OF OBI.
Obi is no more intrusive or restrictive than necessary to provide a proper balance of safety & efficacy.

THE PATIENT CONTINUOUSLY ACHIEVED THE CLINICAL BENEFIT OF OBI.
By compensating for the function of a human arm during meals, Obi successfully restores the patient's function of eating (D550)[1] and maximizes functional independence with an acceptable benefit-risk ratio.

THE PATIENT IS EXPECTED TO OBTAIN LONG-TERM MEDICAL BENEFIT FROM OBI.

☐ **FAIL**

REASON(S) FOR FAILURE AT THIS TIME

SIGN-OFF (***Adobe Sign, DocuSign*** **or hand/wet signature permitted)**	
Full Name (Dr., OTR/L, OTD, etc):	
License#:	
Contact Information:	
Sign:	
Date (MM/DD/YY):	

SECURELY SEND TO: insurance@meetobi.com

[1] *International Classification of Functioning, Disability, and Health: ICF. Geneva: World Health Organization, 2001. R2018.*

STEP 1: SCREENING

Purpose: This step determines whether the patient is an appropriate candidate for Obi.
Instruction: Complete the entire Step1 (grey). Only initiate Step2 (blue) if the patient passes the screening criteria.

Screening Date (MM/DD/YY)	

PATIENT/CLIENT INFORMATION	
Full Name:	
Age (years)	
Birth Sex:	☐ Female ☐ Male ☐ Not comfortable answering

Medical History	**Primary Diagnosis Code (*ICD-10*):**			Other Relevant Diagnosis/ Surgeries / Procedures:
	Diagnosis:			
	Intellectual Developmental Disability Code (*DSM-5*):		☐ NA	
	Diagnosis:		☐ NA	
	Weight (lbs):			
	Recent Weight loss? If yes, explain.			
	Height (in):			

PATIENT'S FAMILY/CAREGIVER/AUTHORIZED REP INFO:	
Full Name:	
Phone#/Email:	
Address:	
Insurance, Primary	
Insurance, Secondary	

FUNCTIONAL EATING STATUS

- ***Eating:*** *The International Classification of Functioning, Disability and Health (ICF) emphasizes independence and self-care in its definition of eating (D550): "The ability to carry out the coordinated tasks and actions of eating food that has been served, bringing it to the mouth and consuming it in culturally acceptable ways…using eating implements, having meals, feasting or dining.";*
- ***Eating Performance:*** *The patient's extent of impaired eating in their current environment.*

	IMPAIRMENT SCALE				
	0, NO PROBLEM person has no problem participating in the function of eating 0-4%	**1, MILD** problem that is present <25% of the time, with an intensity a person can tolerate and which happens rarely over the last 30 days.	**2, MODERATE** a problem that is present <50% of the time, with an intensity, which is interfering in the persons day to day life and which happens occasionally over the last 30 days.	**3, SEVERE** a problem that is present >50% of the time, with an intensity, which is partially disrupting the persons day to day life and which happens frequently over the last 30 days.	**4, COMPLETE** a problem that is present >95% of the time, with an intensity, which is totally disrupting the persons day to day life and which happens every day over the last 30 days
EATING PERFORMANCE					

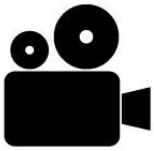
PREVIOUS ASSISTIVE EATING PRODUCTS/TECHNOLOGIES AND ADAPTIVE METHODS		
As listed below, prior to Obi, have all suitable lower cost self-feeding products, technologies and adaptive methods been tested and found to be unsuccessful?	☐ Yes	☐ No

Self-Feeding Equipment Tested/Ruled Out Prior to Obi	If yes, please indicate why needs are not met (Mark all boxes that indicate inability to use equipment):						
	Products/Technologies and Adaptive Methods	Limb Deficiency/ Loss	Impaired Cognition	Paralysis	Impaired Endurance & Strength	Impaired Motor Skills & Coordination	Impaired Pace/Speed
	Adaptive Dishware	☐	☐	☐	☐	☐	☐
	Adaptive Utensils	☐	☐	☐	☐	☐	☐
	Tremor Dampening Utensils	☐	☐	☐	☐	☐	☐
	Arm Supports	☐	☐	☐	☐	☐	☐

Comments:

INDICATIONS FOR USE & RELATIVE CONTRAINDICATIONS		
I confirm that the device's Indications for Use and Precautions have been reviewed (see Obi Instructions for Use: https://meetobi.com/device-documents/) and that based on these guidelines, Obi should be appropriate for my patient to trial.	☐ Yes	☐ No

Sources of Information:			
☐	Medical history/chart review	☐	Clinician assessment



30 second video of use during extended trial (STEP3) highly recommended.

STEP 2: OFFICE ASSESSMENT

Purpose: This step evaluates the patient's safety and effectively with Obi during an in-office assessment.
Instruction: Complete Step 2 (blue) following the assessment.

Assessment Location	
Date (MM/DD/YY)	

Type of Switch(es)	
Activation Site	Please describe the body part used to activate switch(es):

Safety& Efficacy:	☐	**Safety Achieved:** The patient continuously demonstrated safe use of Obi as they have an acceptably low risk of choking, understand the main safety concerns, follow the Instructions for Use, and are expected to continue using Obi safely.
	☐	**Efficacy Achieved:** The patient continuously demonstrated an ability to use Obi as intended with a favorable benefit/risk ratio. Specifically, they performed switch activation to select amongst food groups, bring food/liquid to the mouth, and consume the food in a culturally acceptable manner.

OBI USE, FUNCTIONAL EATING STATUS (D550)

	IMPAIRMENT SCALE				
obi	**0, NO PROBLEM** person has no problem participating in the function of eating 0-4%	**1, MILD** problem that is present <25% of the time, with an intensity a person can tolerate and which happens rarely over the last 30 days.	**2, MODERATE** a problem that is present <50% of the time, with an intensity, which is interfering in the persons day to day life and which happens occasionally over the last 30 days.	**3, SEVERE** a problem that is present >50% of the time, with an intensity, which is partially disrupting the persons day to day life and which happens frequently over the last 30 days.	**4, COMPLETE** a problem that is present >95% of the time, with an intensity, which is totally disrupting the persons day to day life and which happens every day over the last 30 days
EATING PERFORMANCE WITH OBI					

Comments:

RESULT		
	CRITERIA	**NEXT STEP**
PASS	The patient continuously achieved safe and effective use of Obi during the trial.	Please complete an extended/in home trial, then complete Step3.
FAIL	Please **return to the 1st page** and provide the reason(s) for failure.	

STEP 3: TRIAL REVIEW

Purpose: This step confirms whether the patient continuously achieved safe and effective use of Obi through an extended trial period.
Instruction: Perform an appropriate clinical assessment to determine whether the office assessment (STEP2) results were continuously sustained during the trial. Note any significant changes in the "Comments/Observations" box.

Review Date (MM/DD/YY)	

 Video of Use	☐	Please confirm at least a 30 second un-edited video of use was recorded during the extended trial. This is highly encouraged for insurance submission.

Comments/Observations:

SEE 1ST PAGE
for
FINAL DETERMINATION