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| NAME: | **DATE**:  |
| **DOB**:  | **AGE**: |  |
| **Referenced Documents**: Obi Medical Device Needs Assessment |



Figure# : Patient Photo

My name is [INSERT CLINICIAL EVALUATOR NAME] and I am an experienced [INSERT PROFESSIONAL CREDENTIAL: OT/PT/SLP] with an extensive background in assessment of clinical interventions within occupational therapy and expertise in durable medical equipment, including assessment of functional eating (self-feeding) impairment. I am writing this letter of medical necessity for [INSERT PATIENT NAME] (my patient) living with [INSERT DIAGNOSIS] who consequently has severe/complete upper extremity mobility impairment (UEMI). Their UEMI greatly limits their ability to reach age-appropriate developmental milestones and participate in functional ADL activities, including functional eating. Due to their UEMI, my patient needed a functional eating solution assessment. This letter summarizes the results of my clinical assessment, (see Obi MedicalDevice Needs Assessment), including determination of medical necessity, and further justifies these outcomes with support from the published clinical literature.

**About Obi** (according to manufacturer DESIN LLC):Obi is an FDA Class I medical device intended to compensate for the function of a human arm to restore the ADL of self-feeding (functional eating). The following are credentials regarding its widespread use:

* **Safety & Efficacy:**
	+ *FDA* Listing: D253086(Class I).
	+ Clinical Evidence & Human Subject Research:[1] [2] [3]
	+ Medical Safety Certification (*IEC60601-1*):Certified and listed with *SGS North America, Inc. (#F2P22725A-05S).*
	+ Medical Quality Certification (*ISO 13485*):Certified by *Eagle Registrations (Cert#6026).*
	+ Top Industry Honors: *GOLD Medical Design Excellence Award (2018), R&D100 (2016).*
* **Acceptance & Adoption:**
	+ Market entry in 2016;
	+ Several thousand Obis have been recommended by OTs, prescribed by physicians, and funded by the US healthcare system (*Veterans Health Administration, Medicaid*, private insurances, etc.).
	+ Several thousand Obis have been recommended by OTs and funded internationally across more than 20 countries.

**Pre-Screening:** The World Health Organization’s International Classification of Functioning Disability and Health (ICF) defines functional eating and its impairment a disability. The eating definition emphasizes independence (self-care), and specifies 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 a culturally acceptable way [4].” Accordingly, my patient was assessed for their level of eating disability in accordance with the ICF performance assessment framework, which denotes a magnitude of the level of health impairment (e.g. severity of the problem). My patient was determined to have, without a doubt, complete functional eating impairment (complete disability).

While my patient displays the cognitive ability and oral motor control for functional eating, the required range of motion, fine motor precision, and dexterity to hold a utensil to functionally eat is not achievable due to [INSERT DIAGNOSIS]. In such instances, my patient lacks the independence to choose when to eat or drink. Thus, my patient greatly falls below typical developmental standards. Per Center for Disease Control Prevention (CDC), by 12 months old, children are able to use two hands to drink from a cup and begin to spoon-feed independently [5]. The level of support required at mealtime also affects [INSERT PATIENT NAME] developmentally appropriate social engagement with peers in their home, school and community. This often results in missed critical educational and peer-related events that involve food due to the unavailability of assistive technology. Regardless of the environment, social interaction is frequently interrupted by an assisting adult during meals, thus detracting from my patient’s relationships and their overall food intake.

Moreover, my patient was not able to alleviate their eating disability through all lower cost self-feeding products, and adaptive methods such as scooper bowls, adaptive utensils, arm supports or caregiver feeding. None of these options allowed for improved independence and safety. For example, [ADD SPECIFIC EQUIPMENT] does not allow food to be brought to their mouth. In this event, my patient exhibits compensatory movements, such as exhibiting hyperextension of the head and neck, which leads to airway interference and heightened risk of aspiration [6]. My patient demonstrates the same hazardous compensatory pattern while attempting to hold onto and drink from a cup to self-hydrate.

While caregiver assistance may facilitate independent eating with milder forms of UEMI, my patient has a severe to complete disability. For this reason, it is impossible for a caregiver to restore the independence associated with the functions of eating as substantiated by the ICF. Further, the eating experience of my patient is currently dependent on the patience and feeding skill of a caregiver [6] which has health risks for my patient. Unhealthy feeding patterns and forced or fast feeding by others has been respectively linked to complications such as aspiration or aspiration pneumonia [7], malnutrition [8], dehydration [9], pressure sores [10], and gastro-esophageal reflux disease (GERD) [11]. GERD is further associated with pain, while malnutrition and dehydration are associated with increased hospital stay and higher mortality [12] [13] [14] [15]. Physical disabilities are also well documented as predictive of anxiety [16] [17] [18] [19] and depression [19] [20] [21] [22] [23] which may result in a progressively worsening feedforward loop [9] [24]. Therefore, the lower technology products, solutions and adaptive methods leave my patient completely disabled for functional eating performance and way below developmental standards.

Robotics has increasingly emerged as a pivotal component of assistive technology in rehabilitation [25]. A clinical study published in 2025 found that Obi can significantly enhance feeding independence for individuals of a broad age span with UEMI limitations, promoting autonomy, nutritional intake, and social participation. The author goes on to say “Obi has the potential clinical benefit to improve quality of life and to alleviate or prevent medical issues known to be associated with impaired functional eating [1].” For this reason, my patient was then assessed for an Obi. In accordance with the Obi Instructions for Use, my patient was found to conform with all indications, with a favorable benefit-risk ratio.

**Office Assessment:** Following the Pre-Screening, I continued my assessment during an in-office visit at [INSERT FACILITY NAME AND INPATIENT/OUTPATIENT STATUS].

 PRIOR TO OBI, IF THE BASELINE LEVEL OF HEALTH RISKS/IMPAIRMENTS HAS RECENTLY GROWN MORE SEVERE OR WILL LIKELY CONTINUE TO WORSEN DUE TO IMPAIRED FUNCTIONAL EATING, MENTION SO HERE.

My observations are in alignment with well-established findings in the clinical literature see as already stated above (see Pre-Screening).

The device was then individualized for my patient, including: the controlling switch type, location, and body part used for activation. These customizations are appropriate and consistent with the symptoms of the primary diagnosis under treatment. During this assessment, I found [INSERT PATIENT NAME]consistently used Obi safely and effectively to restore and maintain their functional eating performance and age-appropriate development level. It was also possible for my patient to switch to a bowl of water for hydration as needed throughout the meal.

**Post Trial Outcomes:** Following an extensive Obi trial period at home,my patient reliably adhered to Obi during that time, thereby safely and effectively restoring their functional eating performance and associated age-appropriate development with a favorable benefit-risk ratio. Throughout the trial, and over a sufficient number of meals to provide an accurate assessment, my patient managed to consistently eat served food, autonomously, to their contentment or until they were full, without experiencing fatigue or using excessive energy. In such instances, my patient was able to control the coordinated actions of selecting food and water that has been served and bring it to their mouth in a culturally normal way. Therefore, Obi has been undeniably successful at alleviating their eating disability in accordance with the ICF framework.

[INSERT ANY OBSERVED OR DOCUMENTED DECREASE IN SEVERITY OF SYMPTOMS OR RISK FACTORS].

As was demonstrated, Obi provides my patient independence during mealtimes, which fosters psychosocial wellbeing, a critical determinant of health for individuals with severe UEMI [26]. A 2025 study suggests Obi is vital for promoting inclusion and independence in individuals with disabilities, fostering better mental health outcomes [1] . By providing my patient with the control to select and deliver their food, satisfaction and long term restored functional eating are more likely. Studies have also shown that having access to food choices is reflected through stimulus reward values in brain activity [27]. For these reasons, psychosocial experiences must be considered in managing my patient’s condition.

Due to the transportable design of Obi, my patient has the opportunity for improved social participation in critical educational and peer-related events that involve food regardless of the environment (home, school, community). Regardless of environment, while using Obi, the flow of social interaction with peers is age appropriate, thus improving my patient’s social relationships with classmates and their overall food intake. [INSERT SPECIFIC EXAMPLES].

Social participation is crucial in humans to maintain physical, mental, and social well-being [28]. Further, ensuring the development of strong self-oriented social skills is crucial, as deficits in these skills significantly predict the onset of depressive symptoms in children [29].

**Conclusion:** Following a sufficient clinical intervention period to draw an accurate conclusion,my final determination is that my patient showed undeniable improvements after reliably using Obi safely and effectively. [INSERT PATIENT NAME] was able to successfully restore their basic need of functional eating and associated age-appropriate development. For this reason, Obi significantly alleviates their eating disability. I am also confident my patient will adhere to Obi long term and that it is required to continuously maintain my patient’s overall health.

Based upon my documented assessment outcomes and conclusions, Obi cannot be determined as a convenience for my patient, their caregiver, their health care provider, or for cosmetic reasons. After considering potential risks and benefits to my patient, Obi is the most appropriate level of service and can NOT be omitted without adversely affecting my patient’s condition or their quality of medical care. Therefore, I am requesting approval/reimbursement for the following medical device: Obi Robot.

Thank you in advance for your anticipated approval of this much needed medical device for [INSERT PATIENT NAME].

Sincerely,

Name:

Signature:

License#:

Date (MM/DD/YY):

Contact:

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