

munevo Inc.

# Letter of Medical Necessity

for munevo DRIVE

The text provides a sample Letter of Medical Necessity (LMN) that serves as an example of how to use munevo DRIVE with a power wheelchair. However, it is not meant to replace a complete driving evaluation. Any documentation provided by the clinician who orders/evaluates must be tailored to the medical and functional needs of the client, as well as the environments in which they will be used. Additionally, it is recommended that the munevo DRIVE Funding Toolkit is consulted for further funding information.

## Recommended structure of the letter

1. Personal information
2. Background information
3. Current equipment
4. Impact and consequences of disability
5. Munevo DRIVE
6. Supply goals
7. Alternative solutions
8. Conclusion

→ Find **additional information and justification** about munevo DRIVE and additional recommended content on the last pages

## Personal Information

Name:

Age:

DOB:

Diagnosis:

Date:

## Background Information

General information like name, age, diagnosis, history, and any other relevant medical information.

→ “[John Doe] is a [...] y/o [male/female] with e.g. MS who presents to PT for evaluation of medical necessity for addition of alternative drive device to his power wheelchair ...”

Include and highlight:

### Diagnosis details, state of health

→ “[John Doe] has the disease [...] and also suffers from [...]”

### Functional and/or structural damage

- What does the disease affect in this case? (in general)
- Which body parts, extremities, organs are affected by this clinical picture?

- Which body functions and attributes are limited by it (muscle strength, flexibility, endurance, mobility, motor function, pain)?
- What structural limitations are present (Paralyzes, contractures, malpositions, malformations, malpositions, spasms, missing limbs)?

→ “[John Doe’s] [arms] and [legs] are affected, and his [muscle strength and mobility] are severely limited.”

### **Ability dysfunction, impaired and residual activities**

- How do the aforementioned physical limitations affect the physical activities?
- Which activities (walking, reaching, lifting, moving, clicking, steering, holding) are affected by the physical limitations and to what extent?

→ “[John Doe] can no longer [walk] and due to [...], he can only [move his hands for a short time] - moreover, his [... strength] is reduced”

### **Other concerns and limitations about current supply:**

- Environments in which the patient cannot operate a power wheelchair due to lack of hand mobility
- Concerns resulting from missing mobility, missing ability to change seating, missing communication possibilities
- The types of spaces the patient uses at home, in the van/transportation vehicle, and in other settings he routinely uses in the community
- Is the patient permanently dependent on external help?

→ “[John Doe] uses his power wheelchair to access his computer for his work as [...]. He currently utilizes [his joystick] as his mouse and is losing the ability to do this because of [...].”

→ “Due to his [weakened hands], if his hand falls off the joystick [e.g. on uneven grounds], he is unable to bring it back up to the joystick he currently uses to navigate his power wheelchair.”

→ “Due to his weakened breath support/voice control, he cannot navigate [his voice controlled Robotic arm] anymore and thus loses his ability to independently do [...].”

→ “When his system is not working properly, he requires total assistance for [e.g. drinking and taking medications.]”

→ “Prior to [his decline in muscle strength] he was able to perform [most IADLs] with independence or set-up independence [with his robotic arm]. He is currently able to perform the following IADLs with independence or set-up independence with difficulty [utilizing his robotic arm].”

## Current Equipment

- Current power wheelchair and special control (include manufacturer, model, age, driving method and power seating functions if applicable)
- Current seating system, posture in the current system
- Age of current equipment
- **Specific** reasons why current equipment is **not** meeting client’s mobility needs at home and/or in community

→ “[John Doe] has been using [...] power wheelchair with [...] control system and [...] for more than [...] years. He also used the hand joystick for adjusting the seating position of his wheelchair. Due to the progression of his disability and increased motor limitations, he is not able to move and guide his hands independently in a targeted manner. He is permanently assisted by a caregiver, as he cannot navigate at home or change his seating position independently”

→ “[John Doe] requires an alternative control device for his power wheelchair as he is no longer able to operate his power wheelchair with independence due to progression of [e.g. R UE weakness]. Ideally, the alternative control device for his power wheelchair will be one that can [...]”

→ “Of importance in an alternative drive device for [John Doe] is the ability to maintain proportional control. He relies on proportional control for independence in his home with certain tasks [e.g. grooming/hygiene/self-feeding/accessing his computer for work/accessing his community].”

→ “Without proportional control, he would be unable to access [e.g. his bathroom] safely and independently, increasing the number of hours of assistance he requires during the day.”

### Chin control

→ “[John Doe] currently drives with a chin control. Only indoors this is possible without any problems. Outdoors, many hurdles arise that prevent [John] from living his daily life the way he wants to. There are many bumps on sidewalks that cause the chin control to hit uncomfortably against the chin, shift, and have a delayed response. Since [the spinal

fusion in September], the chin controls have been very difficult for him to use. The typical movement of the head to steer is now difficult due to the limited range of motion in the upper body. Driving longer distances is currently impossible with the control system. [John] is also unable to adjust the seat of his wheelchair himself. When he adjusts the seat, the chin control no longer sits in the correct position and has to be positioned there. So he is not able to get out of this situation on his own."

### **Head array**

→ "[John Doe] currently drives with a head array. Only indoors this is possible without any problems. Outdoors, many hurdles arise that prevent [John] from living his daily life the way he wants to. There are many bumps on sidewalks that cause the head array to hit uncomfortably against the head, shift, and have a delayed response. his seating is constantly changing, the head controls have been very difficult for him to use since he cannot adjust it by himself. The typical movement of the head to steer is now difficult due to the limited range of motion in the upper body. Driving longer distances is currently impossible with the control system. [John] is also unable to adjust the seat of his wheelchair himself. When he adjusts the seat, the head control no longer sits in the correct position and has to be positioned there. So he is not able to get out of this situation on his own."

### **Mini Joystick**

→ "[John Doe] currently drives with a mini joystick control. Only indoors this is possible without any problems. Outdoors, many hurdles arise that prevent [John] from living his daily life the way he wants to. There are many bumps on sidewalks that cause his hands to lose the contact to the mini joystick control due to the gravitational shift, and thus he needs help from someone to put his hand in the right position. Since the disability is progressing, the mini joystick controls have been very difficult for him to use. The typical movement of the hand to steer is now difficult due to the limited range of motion in the hands. Driving longer distances is currently impossible with the control system. [John] is also unable to adjust the seat of his wheelchair himself. When he adjusts the seat, the mini joystick control no longer sits in the correct position and has to be positioned there. So he is not able to get out of this situation on his own."

## **Impact and consequences of disability**

- In what areas of daily life do these ability disorders limit the patient ? (general)
- Everyday activities that the patient has stopped doing/participating due to inability to operate power wheelchair, seating adjustments or communication devices (e.g. smartphone) when in specific environments

- E.g. independent living: movement in the apartment, terrace, changing rooms, walking (fresh air), walking the dog, visiting relatives/neighbors, hygiene, opening doors, emergency situations (warning lights, emergency contact), adjusting sitting position, online ordering (groceries & other).
- E.g. mobility: shopping, groceries, doctor appointment, therapist, bank, bakery, pharmacy, post office, (escape hazardous situations, move inside when it rains or outside because of the heat, etc...). → specifically name stores nearby.
- E.g. mental quality of life: communicating with other people (making phone calls, writing messages), watching TV, using social media, using the internet, working, reading newspaper/news, listening to music → which newspaper, which channels...?
- E.g. children: playing, going outside, meeting friends, going to school, homework, social contacts

## munevo DRIVE

- Introduce the munevo DRIVE solution
- Name arguments as to why munevo DRIVE is better than other solutions (e.g. more independence, Add-Ons, ...)
- Explain the different Add-Ons of munevo DRIVE

→ *“I recommend munevo DRIVE to be added to [John Doe’s] new (or current) power wheelchair, to address the following concerns when he is operating his power wheelchair. When equipped with munevo DRIVE, [John Doe] will be in full control of his mobility, but will be prevented from losing the ability to drive his power chair as munevo DRIVE can be adapted by himself and due to his [changing seating position; driving over bumps; driving outside; cognitive impairment; etc.]. munevo DRIVE will allow [John Doe] to be a safe and functional independent driver of his power wheelchair both in his home and community.”*

→ *“munevo DRIVE is a state-of-the-art, FDA approved, bluetooth connected proportional drive control. It is a set of smart glasses with accelerometer/gyroscopic technology similar to that found in a smartphone. The accelerometer/gyroscope translates head motions into display control, drive function, and seating functions and is proportional based on displacement from a calibrated "center". Additionally, munevo DRIVE can be programmed to control other devices such as a robotic arm, a computer, a cell phone, and features of a smart home.”*

→ *munevo DRIVE will compensate for motor limitations and changing seat positions through onboard calibration, position change alerts, and drop detection. munevo DRIVE will allow the client to be independent with powered mobility versus relying on a caregiver to control a power wheelchair and/or constantly have to adjust the seating to fit the fixed control systems.*

→ *“Because the glasses of munevo DRIVE are attached to the patient and not the chair, when he loses position in the chair, he is able to stop and access his seating menu and perform self-repositioning independently.”*

→ *“Despite limited functions [e.g. cervical protraction and retraction], [John Doe] is still able to operate the munevo DRIVE glasses as these motions are not necessary for operation.”*

→ *“With munevo DRIVE [John Doe] demonstrated the ability to independently access and select options from the menu of his power wheelchair utilizing head motions with this device.”*

→ *“With munevo DRIVE, selection of menu options is completed with cervical rotation and drive control and seating functions are operated via cervical side bend. While in side bend, the patient is able to perform cervical rotation to survey his environment without loss of drive or seating operation.”*

→ *“In regards to the connectivity to other devices, the munevo Drive can connect directly via bluetooth to the patient's smartphone (ios & Android) via an included feature called munevo PHONE, directly via bluetooth to the patient's robotic arm in an included feature called munevo ARM, and directly via bluetooth to a smart home in an included feature called munevo HOME. It is also able to connect to his computer for mouse and keyboard control. This connectivity sets this device apart from all other proportional devices in regards to his ability to remain and even gain independence within his home.”*

## **munevo PHONE**

→ *“[John Doe] will be able to independently use his phone to call 911 in case of emergency. The ability to call 911 in an emergency is vital to remaining independent at home.”*

→ *“Should he be unable to utilize his voice, if he were to call 911, because the call is being made from a smartphone, emergency services will still be dispatched to his*

*location based on the GPS signal of his phone.”*

*→ “In addition to calling 911, he will also be able to call his own doctors to make appointments and call [someone e.g. the clients he works with] which will allow him to remain independent in these areas as well.”*

## **munevo ARM**

*→ “The ability of the device to connect to his robotic arm will have a huge impact on his independence at home as well as in the community.”*

*→ “It is to be expected that he will be able to perform the following MRADLs independently: [...]”*

*→ “He was/will be also independent or set-up independent with the following IADLS: [e.g. taking medications, opening doors, pushing handicap accessible entrance buttons, retrieving and transporting objects, picking objects up from the floor, navigating through a store - carrying selected items and paying for them at checkout, turning pages of a book, eating out at restaurants.]”*

*→ “With the direct bluetooth connectivity of the Munevo DRIVE to his robotic arm, it can be expected that he regains independence in all of the above listed MRADLS and IADLS.”*

*→ “Control of his robotic arm and the menu for the robotic arm will be through the same head motions as driving with which he demonstrated independence and ease.”*

## **munevo HOME**

*→ “This device can connect to a smart home which will allow him to independently do tasks at home [e.g. regulate the temperature of the home/raising and lowering of shades/ turn on and off lights as needed for safe driving throughout his home at night or other low lit conditions/ operate the automatic doors in the home more easily rather than using either his robotic arm or contacting his chair to the button].”*

## **Supply Goals**

- Include goals specific to the client that support safety and independence in mobility and with ADLs, both in the home and community.
- What would be the patient's wish regarding the aforementioned daily activities?



- How can it be achieved that the patient can perform these activities again?
- What is the goal of the supply with munevo DRIVE - How can munevo DRIVE help achieve these goals?
- How can munevo DRIVE Add-ons (Smartphone, Robotic arm, Smart Home, Infrared or Bluetooth control) help achieve these goals?

→ “[John Doe] would like to be [independently mobile again] to be able to [move freely around the house] and [go for a walk in the nearby residential area]”

→ “[John Doe] needs [the munevo DRIVE special control] for his wheelchair because [he can no longer drive with the remaining muscle strength in his hands]. He also has [back problems/pain] and needs [a way to adjust his backrest independently].”

→ “The goal is to provide [John Doe] with a power wheelchair that includes munevo DRIVE, to achieve the highest level of independence with powered mobility and so [John] can perform the following activities again: [...], [...] and [...]”

→ “[John Doe] tested the special control system munevo DRIVE. This is practical and sufficient, meets the objectives mentioned above and he got along very well with the control. All other control systems have either been tested or ruled out.”

## (Less Costly) Alternative Solutions

- Name (less costly) alternative solutions and argument why they are not sufficient for the patient
- What advantages does the patient have with the munevo DRIVE solution?
- Explain possible cost savings with munevo DRIVE

### **Proportional control:**

→ “Because proportional control is of utmost importance, all proportional controls were considered. As noted in the trial/considered section of the evaluation, he is unable to utilize any of the typical proportional controls due to limitations in his physical function.”

### **Mini Joystick at hand**

→ “[John Doe] is unable to utilize a mini joystick at his [R] hand due to his current motion being from [gross motion at his shoulder]. Mini joystick control requires fine motor control at the hand which he does not have. The gross motion at his shoulder will be unsuccessful in operation of a mini joystick regardless of the amount of throw necessary to operate it.”

### **Mini Joystick at the chin:**

→ “[John Doe] does not have adequate strength/endurance in cervical musculature to effectively operate a mini joystick at his chin. He is unable to perform [e.g. cervical protraction and retraction] successfully. To control motion left and right it requires cervical rotation.”

→ “Even though he can move his neck and has enough strength, it's important to know that he often needs to take his chin off the joystick during daily tasks like surveying his environment, talking to others, or crossing the street. The problem is that he doesn't have enough cervical strength to reposition his chin back on the joystick effectively.”

### **Proportional Head Array**

→ “[John Doe] does not have adequate strength/endurance in his cervical musculature to hold pressure on the mechanical pads for driving. Additionally, he frequently loses position in the chair, [e.g. sliding anteriorly] and when this happens, he would no longer be able to access the head pads.”

→ “This eliminates his ability to access the seating function control on his power wheelchair so he is unable to reposition himself successfully and is unable to drive.”

→ “He is unable to perform [a specific motion e.g. cervical retraction] and is therefore unable to access the posterior pad for driving.”

### **Non-proportional control**

→ “Despite the significant loss in independence that would occur with non-proportional control, all options were considered due to the costliness of the munevo DRIVE. It was determined that **no** non-proportional drive controls were appropriate due to the patient's physical inability to use them.”

### **Non-proportional Head Array**

→ “[John Doe] frequently loses position in the chair, [e.g. sliding anteriorly] and when this happens, he would no longer be able to access the head pads”

→ “This eliminates his ability to access the seating function control on his power wheelchair so he is unable to reposition himself successfully and is unable to drive.”

→ “Due to the nature of non-proportional devices, more motions are required to keep on a straight path. These frequent motions are difficult for [John Doe] over time due to [e.g. muscle fatigue].”

### **Sip and Puff**

→ “[John Doe] is unable to utilize sip and puff devices due to limited respiratory capacity with [e.g.diaphragmatic involvement of MS].

### **Eye Gaze**

→ “Not appropriate due to ability to control drive/seating functions with cervical musculature”

### **Cost savings**

→ “In addition to the proportional drive control and the connectivity features, the **cost savings over time** of the munevo DRIVE solution should be considered. Due to the fact that the munevo DRIVE is not attached to the wheelchair, but attached to the user, there is no wear and tear on the chair, no additional moving or mechanical parts and therefore reduced chance of costly repair to the chair. The munevo DRIVE is also easily recalibrated should the patient start losing cervical function, so a new device would not have to be considered unless the patient lost all cervical function as it only requires 3 degrees of side bend and rotation for operation and the starting position is the patient's resting position. In patients with MS, the cervical control/strength is one of the last areas in which a patient will lose strength/control with the majority of patients retaining enough function to operate this device.”

## Conclusion

It is important to emphasize the functional impact of the client's limitations and to show how munevo DRIVE enables independent mobility for the user, restoring the ability to pursue certain daily activities and thus enhancing the user's quality of life.

→ *“With all options considered, the munevo DRIVE is the most appropriate option for [John Doe] due to its proportional control, his ability to control seating functions and drive control independently throughout the day regardless of his positioning in the chair, and also it's connectivity to the patient's devices.”*

→ *“In summary, after considering all less costly alternatives, the munevo DRIVE is the most appropriate device for this client based on his need for [ e.g. head operated proportional control], his inability to utilize other proportional and non-proportional control, and his need for connectivity to his other devices to regain/gain/maintain independence in MRADLs and IADLs”*

→ *“As a result of [list the specific concerns], [John's] ability to drive a power wheelchair independently and safely are decreased, as well as the independent change of the seating position or the use of a smartphone. A power wheelchair equipped with a munevo DRIVE special control system will allow [John] to be independent in his home and all other common environments vs. being dependent on a caregiver for mobility and aforementioned activities. Feel free to contact me with any questions or further needs.”*

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Clinician Printed Name

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Date Signed

I have read the above evaluation report and concur with the recommendations therein. I follow this client for medical care.

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Physician Printed Name

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Date Signed

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NPI

If you have any questions, please call **+1 646 7818074** or send a mail to **[sales.us@munevo.com](mailto:sales.us@munevo.com)**.

## Additional information about munevo DRIVE

**The funding sources may not be familiar with the munevo DRIVE technology, so it is crucial to provide a clear and precise definition of this technology in your documentation.**

Munevo DRIVE is an innovative proportional head control for electric wheelchairs for people who experience motor limitations and whose hand function is very limited or no longer available due to injuries or diseases. It is based on smart glass technology and helps people with limited mobility to achieve independent mobility and more self-determination by controlling their wheelchair using head movements.

Motion sensors inside the smart glasses detect even small movements of the patient's head and convert these into control commands that are passed on to the electric wheelchair via the munevo DRIVE adapter attached to the wheelchair. Thus, the patient can not only control the wheelchair independently but can also adjust the seating position of the wheelchair self-sufficiently. Beyond controlling the wheelchair, various munevo Add-ons allow the patient to also control a cell phone, computer, TV, robotic arm mounted on the wheelchair or smart home systems. The smart glass can be recalibrated anytime by the patient in a short time to fit the personal range of head motion. While using munevo DRIVE, the user receives visual feedback on navigation in the menu, driving and usage of the other features in the display of the smart glass.

munevo DRIVE offers advantages over conventional solutions such as mechanical head controls. These are usually attached to the wheelchair, cannot be adjusted independently and are therefore uncomfortable and stigmatizing. munevo DRIVE, on the other hand, provides freedom and independence for the user.

munevo DRIVE is an approved medical device which is already registered with the FDA. In Germany and other European countries, it has already been reimbursed by health insurance companies since 2019.

### Mobility

If a new power wheelchair is recommended, include results of mobility evaluation and all recommendations including things such as drive wheel configuration, tracking technologies, driving method, and power seating. The justification should support each item based on individual medical needs. If adding munevo DRIVE to a current power wheelchair with special control, be specific as to what needs are not being met and why the client cannot function safely and independently without munevo DRIVE.

## Additional Justification

- munevo DRIVE is characterized above all by the fact that it can be **easily adapted** by the user.
  - Calibration function allows the user to adjust the sensor sensitivity to their own needs and range of motion, both for the menu navigation and the driving gestures.
  - In the case of advancing diseases with reduced movement ranges, the user still retains the complete functionality of the control.
- munevo DRIVE is **body-fixed**, as the smart glass is directly connected to the head. If the user's sitting position changes in the wheelchair (e.g. standing function of wheelchair), permanent control of the wheelchair is still guaranteed, compared to a wheelchair-fixed control, which can no longer be reached.
  - munevo DRIVE allows and supports independent position changes to avoid pain or collateral damage (e.g. decubitus, pressure injuries).
  - Users can change sitting positions and are not dependent on help.
  - The previous, very time-consuming, optimal positioning of the user by the nursing staff or relatives, so that the occipital control can still be reached, is no longer necessary.
- Different **driving modes** (indoor & outdoor) allow optimal speed adaptation to the environment and safe navigation both in confined spaces and outdoors during longer journeys.
- With software upgrades, which do not require any further complex hardware, munevo DRIVE **can be extended** to control smartphones, computers, SmartHome systems as well as robotic arms (e.g. Kinova Jaco).
  - Autonomy and independence, even in addition to wheelchair driving.
  - Opens up communication possibilities and an increased quality of life.
- Lightweight, **less noticeable** and comfortable smart glass:
  - nothing in the face of the user that disturbs as with conventional control (e.g. chin control), making it easier to drink and eat.
  - Pushing the head forward to reach a chin control, is not conducive to posture. munevo DRIVE, on the other hand, supports a healthy, upright posture and works against kyphosis.
  - The risk of injuries to the chin, mouth, lips or even the teeth through the chin joystick is eliminated when using munevo DRIVE.
- More information can be found at [www.munevo.com](http://www.munevo.com).

## Additional recommendations for the LMN

**History** - When compiling the medical history, make sure to include details regarding symptoms, past pressure injuries, clinical progression of the diagnosis, and any other relevant conditions such as respiratory, cardiac, and pain management.

**Physical Exam** - During the physical examination, the results of the supine and seated assessments conducted outside of the wheelchair should be documented. This should include information on the person's sitting balance, postural support requirements, and level of sensation. Additionally, range of motion, strength, and coordination should be noted.

**Functional Assessment** - In the functional assessment, describe the individual's ability or inability to perform transfers, self-generate mobility, and complete activities of daily living.

**Environmental Assessment** - During the environmental assessment, describe the person's current living situation and note the accessibility of entrances and exits, as well as any accessibility limitations in the home or community. Information about transportation options should also be included.

### Components

1. **Power wheelchair**: Include Manufacturer name and model  
→ List all options with individual medical justification
2. **Seating System**: Include Seat/Back Manufacturer name(s) and models
3. **munevo DRIVE special head control** for power wheelchairs to enable self-sufficient mobility for users who experience motor limitations and whose hand function is very limited or no longer available due to injuries or diseases. Please see additional information in the Evaluation section above.
4. **munevo DRIVE Addons** for supplementary functions that enable everyday activities and participation in social life (Smartphone, Robotic arm, Smart Home, Infrared or Bluetooth control)
5. Any other required **components/accessories** listed with individual medical justification