Describing LUCI

WHEN DOCUMENTING CLINICAL JUSTIFICATION

Many funding sources may not be familiar with the LUCI technology. **We have seen that a concise, effective product description linked to the user's experience and functional mobility needs improves the likelihood of a LUCI approval.**

These descriptions should **be carefully reviewed to ensure they are sufficiently tailored to the end user**. LUCI recommends that you also consult the Funding Toolkit, the LUCI Letter of Medical Necessity (LMN) Guide, and learn how to share the specifics of an ongoing case with use at **luci.com/funding/**.

Description of LUCI Core Functionality

Please ensure that bolded areas are tailored to your client's specific information.

Based on a LUCI trial that took place on **[DATE]** at **[LOCATION]**, I believe LUCI will increase **[NAME]**'s functional independence at home and in **[his/her]** community by allowing **[him/her]** to safely use **[his/her]** power wheelchair in all environments without constant supervision and caregiver assistance/intervention. Before I share how **[NAME]**'s driving improved with the addition of LUCI, I want to explain what LUCI is and how the core functionality will be critical to **[NAME]**'s current power wheelchair.

LUCI is an accessory to a power wheelchair. It mounts directly onto **[CLIENT'S MAKE AND MODEL]** chair base and integrates directly with the wheelchair's electronics. LUCI provides advanced driver assistance through sensors that conduct a 360° scan of the chair's environment 10 times per second. The sensors can identify stationary and moving obstacles, such as furniture, walls, and people, as well as, unsafe drop-offs, such as stairs, curbs or the edge of a ramp. The LUCI software will intervene to slow and then, when needed, stop the chair to prevent collisions and tip-overs with said obstacles and drop-offs.

LUCI's software relies on three types of sensors, radar, ultrasonics, and camera-vision with infrared, to triple-check the chair's surroundings. If the chair is headed towards an obstacle or unsafe drop-off, LUCI's software is customized to the driver and will intervene by scaling back the driver's input to the joystick to slow the chair down allowing the user time to navigate away. This 'driver assist' functionality, of slowing the chair before a collision or, for example, driving off a curb into traffic, gives the driver sensory cues (the slowing of the chair and a light on LUCI's user interface), that call the driver's attention to their immediate surroundings. If the driver is unable to redirect their driving path because of **[INSERT CLIENT DEFICIT/EXAMPLE]**, LUCI will completely stop the chair to prevent a collision or tip-over and prevent possible injury and wheelchair damage.

Because LUCI can detect moving people and obstacles around the chair, LUCI will automatcally pace to the speed of the power wheelchair to meet the speed of the crowd when in busy environments, i.e. in a crowded school hallway, at a doctor's appointment, or **[INSERT ACTIVITY RELEVANT TO CLIENT]**.

To maximize your success, focus on the mobility activities that LUCI most positively impacts for your client. Tailor each example to your client's unique experience and their specific mobility needs.

Please see two real justification examples of how to do this at the bottom of this document

LUCI's Crowd Confidence increases driver efficiency and reduces fatigue over a full day of chair use because the driver can move through the crowd without providing constant changes to the drive input.

LUCI is NOT Experimental

Please include the following language and attach LUCI's FDA registration to your submission. You may also familiarze yourself with the payor's definition of experimental and state how LUCI meets that definition.

LUCI is an accessory to a power wheelchair and is an FDA Class I, exempt medical device that meets the associated requirements of the FDA and FCC. In addition, LUCI meets the applicable requirements of IEC 60601 for home use medical electrical equipment. Please see attached FDA registration.

Find LUCI FDA Registration Document and attach it to your submission at luci.com/funding/.

Beyond describing LUCI's Core Functionality to the reviewer, it is most important to **focus on the mobility activities that LUCI most positively impacts for your client.** In your justification of LUCI, **clearly link how these 1-3 specific mobility activities will be realized through the addition of LUCI,** rather than trying to explain every component of the LUCI system.

The remainder of this document lists the unique, customizable features of LUCI for you to include **as they are relevant to your client's** most important mobility activities.

The Dashboard: LUCI's Driver Interface

If the funding source wants to understand how the driver is able to control/interact with LUCI, please draw from this desciption of the Dashboard.

The LUCI Dashboard consists of one button and four indicator lights and is the driver's main interface with the LUCI system. These four indicator lights show: if LUCI is personalized to the power wheelchair driver, two optional connectivity status indicators, and to let the driver know when the LUCI sensors are detecting an obstacle or unsafe drop-off. This driving indicator changes color to let the driver know that LUCI has detected an obstacle or unsafe drop-off in the driving path. The LUCI button on the Dashboard can perform many functions, from Override (see below), to launching the LUCI Setup Tool, silencing sounds, and even sending reports back to LUCI engineering for improved on-going service.

There is an auxiliary port on the Dashboard so that access to the LUCI button is available through a switch control that can be mounted anywhere on the chair based on the driver's abilities.

LUCI Clearance & Override

Knowing how far away LUCI stops and if and when LUCI can be turned off is a common question from payors. Please review and tailor the following based on the specifics of your client's case.

LUCI allows adequate clearance on all sides of the chair for easy navigation within the home and community. In standard settings LUCI stops between 2-4" away from obstacles in the front and the back, depending on the speed of approach. The front and back stopping parameters can be adjusted in the LUCI Setup Tool to accommodate stopping at a comfortable and safe distance. LUCI also has a 1" clearance on the sides of the chair to ease navigating through narrow doorways or tight areas.

How ever you plan to setup Override for your client, ensure you describe how your client will still be safe.

Should there be a moment when the driver needs to turn LUCI off in order to, for example, get close enough to their bed to transfer, push through a closed door, or **[INSERT CLIENT EXAMPLE] [he/she]** can temporarily disable the sensors by pressing the LUCI button to override the system. The Override function is customized to the driver based on what the clinician, care team, and driver detemine is best.

If the care team has concerns about the driver having access to Override, a switch can be plugged into the the dashboard and programmed to be the only access to override and mounted on the back of the chair.

For driver's in chairs outfitted with an attendant joystick, the attendant can opt to have LUCI off the entire time the chair is in the Attendant Joystick Profile.

Customizing LUCI to the Driver

LUCI provides a number of customizable functions and a growing feature set. While funding sources may not be interested in all of these points, there may be some that will make LUCI an essential addition for your client!

Power wheelchair drivers are able to tune their LUCI system to meet their needs across a number of features:

» **Reaction Time**
LUCI captures the wheelchair driver's reaction time and adjusts the rate of its slowing accordingly. For example, when a driver has a slower reaction time LUCI will intervene and slow the chair sooner and more gradually, giving the wheelchair driver time to navigate away from the detected obstacle or drop-off. For a driver with a faster reaction time LUCI will allow the driver to get closer to an obstacle or unsafe drop-off before intervening. This keeps the world within the driver's ability to react to it.

» **Wheelchair Parameters**
For wheelchair drivers with longer footplates, larger footboxes, or with equipment on the back of their chair, LUCI can adjust its stopping parameters in the front and the back of the chair to accommodated different virtual footprints.

» **White Cane Filter**
This feature was designed specifically for any drivers that use a white cane to navigate the world. With White Cane Filter enabled, LUCI can filter out the repetitive swooshing motion of a white cane so that LUCI can continue to drive smoothly. LUCI will still be able to detect all the other obstacles except for the driver's white cane. **[INSERT EXAMPLE SITUATIONS WHERE LUCI'S DETECTION - SIDEWALKS, DOORWAYS - WILL POSTIVELY IMPACT THE DRIVER'S MOBILITY.]**

» **RampAssist™**
The RampAssist™ feature utilizes LUCI's cameras to follow a pre-determined pathway up and down the very narrow ramps in most transportation vehicles. It will align the chair and help to eliminate caster flips when entering and exiting a vehicle by ramp.
While LUCI's drop-off protection is always active on a ramp, this additional feature ensures the chair drives up the center of the ramp every time rather than the driver having to continually make adjustments to the drve control in an effort to remain centered on a narrow vehicle ramp that does not have side rails.

Access to the MyLUCI App

Review the additional features offered in the MyLUCI App. If they are relevant to your client being successful in using LUCI, you may want to include a tailored version of those features in your LMN.

The MyLUCI App is availabe for both Apple and Android phones and is available for download in the iOS App Store or Google Play Store.

While not required for LUCI to work, the MyLUCI App opens up another a world of accessible features to the LUCI user. The MyLUCI App tracks battery usage, miles driven each day, and how many collisions and tip-overs were prevented. It can enable the driver with better information in the following areas:

» **Share Data and Emergency Notifications with Your Support Team**
By adding Support Members in the MyLUCI App, the family and care team can receive a push notification or email from the MyLUCI app if the user's heart rate spikes, if wheelchair runs out of battery, etc. For example, if the driver runs out of battery LUCI will send a GPS-location of where the incident happened to the MyLUCI Support Team Members.

» **LUCI View Visualizer**
Inside of the MyLUCI App, users can view a live feed of what the sensors are detecting in each moment. As with all other LUCI Features, because this is 360-degrees LUCI users will use this like a backup camera, enabling drivers to back into bathroom stalls or elevators without worry.

» **Health wearables integration**
LUCI connects to the Apple watch, Fitbits, and more and will notify Support Members if the driver's heartrate goes outside of a healthy range, which could indicate **[INSERT SPECIFIC SITUATION RELEVANT TO YOUR CLIENT].**

» **Skin Health Notifications**
MyLUCI App users can setup a skin health plan with the help of their clinician inside of the app. Based on their stated plan, the MyLUCI app will send the driver push notification reminders when it is time to offload helping with greater compliance and preventing costly and painful compression sores.

Three Year Manufacturer Warranty

While a less common request from payors, some do ask about repairs and warranty coverage.

LUCI guarantees our system with an industry-leading manufacturer warranty of 3 years, which you can read in full at luci.com/legal/. For any questions, reach out to a LUCI expert at support@luci.com or at +1 (615) 813-5824.

Examples From A REAL Sample Clinical Justification Letter

Both of these examples are from a successful LUCI justification that directly connected the LUCI core features to the unique experience, needs and functional mobility of the client.

To have a successful LUCI submission, it is essential that the clinician writing the letter take throughful steps to tailor their descriptions to their specific client. These are examples are NOT meant to be copied into the funding application.

Linking LUCI's Core Features to the Client - Obstacle Detection

LUCI's software will scale back **[NAME]**'s input to the joystick to slow and then stop the chair, when needed. LUCI's 360° collision avoidance is looking out for any obstacles, like walls, doorways, furniture, or other people when driving down the busy hallways at school that have been a struggle for **[NAME]** to navigate during trials because of **[his/her]** impaired coordination, impaired motor planning,

slowed reaction time, and fluctuating tone in **[his/her]** upper extremities. With LUCI on **[NAME]**'s power wheelchair, if an obstacle appears in the path where **[he/she]** is driving, LUCI will slow the chair down and a light will appear on the user interface - the slowing of the chair AND the light on the LUCI Dashboard are both alerting **[NAME]** there is an obstacle nearby; this cues **[NAME]** to scan **[his/her]** environment as best **[he/she]** can to try and navigate around the obstacle. LUCI slowing the chair down as it approaches obstacle/s gives **[NAME]** time to course-correct independently. This feature is programmed based on **[NAME]**'s actual reaction time so that **[he/she]** is given adequate time to course-correct based on **[his/her]** motor skills. However, if **[NAME]** is unable to remove **[his/her]** hand from the joystick in a timely manner LUCI will intervene and stop the chair before it collides with an obstacle. Some examples of when **[NAME]** would benefit from LUCI's intervention are if **[he/she]** is experiencing a spasm and is not able to course-correct; OR if **[he/she]** is unable to see the obstacle due to **[his/her]** impaired trunk control and difficulty turning to see what is behind/below **[him/her]**; OR a moving obstacle around **[him/her]** jumps in front of the chair faster than **[his/her]** ability to react to it. In all of these situation, LUCI will keep **[NAME],** the power wheelchair, and the people and obstacles in **[NAME]**'s environment safe while enabling **[NAME]** to have independence in **[his/her]** power wheelchair.

Linking LUCI's Core Features to the Client – Drop-Off Protection

LUCI is looking out for unsafe drop-offs 360° around the power wheelchair, like the edge of a sidewalk or ramp. The power wheelchair being requested can safely climb **[~3"]** and LUCI is aware that the world is not flat. LUCI will not limit this level of climbing to ensure **[NAME]** can safely navigate **[his/her]** home, school, and community. For example, LUCI will not limit the chair to drive over a threshold in **[NAME]**'s home, onto the lip of a ramp at school, or onto the wheelchair platform to board the bus. Instead, LUCI can distinguish between these examples of safe drop-offs and any unsafe drop-off greater than **[~3"]**, which could result in a tip over of the chair and driver. Due to **[NAME]**'s impaired coordination, impaired motor planning, slowed reaction time, and fluctuating tone in **[his/her]** upper extremities, safely navigating a ramp or driving along a sidewalk would require constant supervision and intermittent hand-over-hand assistance to ensure **[NAME]** did not drive over the edge – with LUCI, **[NAME]** can be completely independent in **[his/her]** power wheelchair in these environments that he will face daily going to school.

Detecting curbs and drop-offs is a challenge for **[NAME]** due to **[his/her]** impaired trunk control and cervical rotation to the right that makes turning to see what is behind or below **[him/her]** difficult when sitting in the power wheelchair. When an unsafe drop-off is detected by LUCI compensating for **[NAME]**'s impairments, LUCI will slow **[NAME]**'s power chair down and a light will appear on the user interface, alerting **[NAME]** there is an unsafe drop-off nearby and giving him time to course-correct independently. This feature is also programmed based on **[NAME]**'s actual reaction time so that **[NAME]** is given adequate time to course-correct based on his motor skills and ability to interpret stimuli. However, if **[NAME]** is not able to course-correct in a timely way OR is unable to remove **[his/her]** hand from the joystick due to **[his/her]** multiple upper extremity deficits OR is unable to detect the edge of a sidewalk or height of a drop-off to know whether it is safe or not, LUCI will intervene and stop the chair. This LUCI intervention will keep **[NAME]** and the power wheelchair safe. LUCI would remove the need for contant supervision and allow **[NAME]** independence in **[his/her]** power wheelchair with LUCI compensating for **[his/her]** impairments. According to Onyango et al. in a publication from 2016, "In spite of the presence of powered wheelchairs, some of the users still experience steering challenges and maneuvering difficulties that limit their capacity of navigating effectively. For such users, steering support and assistive systems may be very necessary" - this is where LUCI comes in.

Because LUCI can detect moving people and obstacles around the chair, LUCI will pace the speed of the power wheelchair when in crowds or busy environments. This feature become essential in **[NAME]**'s school hallway during class change, enabling **[him/her]** to their classmates seamlessly without fear of injuring themselves or others, and without having to provide constant changes to the drive input. This is important as those constant changes to the drive input in these environments add up throughout the day and contribute immensely to driver fatigue. This feature allows drivers to save their energy for the tasks that are meaningful to them, such as bathing or preparing a meal. This also decreases driver anxiety in these scenarios which, for **[NAME]** would result in less extensor tone spasms throughout the day and **[NAME]** feeling confident to navigate busy environments independently rather than needing someone else to take over driving.

Explore more funding resources at luci.com/funding/

Reach out to us directly at 615-813-LUCI (5824) and support@luci.com