ENCLOMIPHENE TREATMENT AGREMENT

- THIS INFORMED CONSENT FOR ENCLOMIPHENE (THE "CONSENT") SETS FORTH THE TERMS AND POLICIES FOR THE CLINICAL SERVICES PROVIDED BY SUPERPOWER MEDICAL GROUP OF CA PC, A CALIFORNIA PROFESSIONAL MEDICAL CORPORATION, AND OTHER THIRD-PARTY MEDICAL GROUPS (THE "MEDICAL GROUPS") THROUGH THE ONLINE TECHNOLOGY PLATFORM ("PLATFORM" OR "SUPERPOWER PLATFORM"), WHICH IS OWNED AND OPERATED BY SUPERPOWER HEALTH, INC. ("SUPERPOWER").

  This informed consent is for the use of enclomiphene, a prescription medication, for the treatment of hypogonadism in males. The purpose of this consent is to provide you with information about the risks, benefits, and safety considerations associated with enclomiphene treatment in order for you to make an informed decision as to whether or not to proceed with treatment, as well as to obtain your agreement to adhere to the treatment protocol as prescribed by your Medical Group healthcare provider (“Healthcare Provider”). Please read this form carefully and ask any questions you have before signing.

  GENERAL INFORMATION
  Enclomiphene is an FDA-approved medication that has garnered attention for its application in the treatment of hypogonadism in males. It is an isomer of Clomiphene Citrate (brand name: Clomid), an FDA-approved medication for the indication of ovulatory dysfunction in women desiring pregnancy, but which is also used off-label by men as an alternative to testosterone replacement therapy to avoid the side effects of TRT, such as testicular shrinkage and decreased sperm production. Unlike Clomiphene Citrate, enclomiphene's potential in managing low testosterone levels is a newer exploration. Enclomiphene works by influencing the delicate balance of hormones within the hypothalamic-pituitary-gonadal (HPG) axis, which plays a central role in regulating reproductive and sexual function in men.Enclomiphene is a non-steroidal estrogen receptor antagonist. Enclomiphene binds and occupies the estrogen receptors in the pituitary gland of the hypothalamus, thereby preventing estrogen from binding and promoting the release of gonadotropins (FSH & LH). The increase in FSH and LH stimulates the Leydig cells in the testes to secrete more testosterone. This is a marked difference from testosterone replacement therapy, which shuts down the body’s natural production of testosterone and replaces it synthetically.

  RISKS AND SIDE EFFECTS
  While enclomiphene can potentially improve symptoms associated with hypogonadism, it may also cause side effects. Common side effects include, but are not limited to:

  • Headache
  • Nausea
  • Diarrhea
  • Common cold
  • Hot flush
  • Joint pain
  • Dizziness
  • Muscle spasms
  • Fatigue
  • Increased appetite
  • Aggression
  • Irritability
  • Acne
  • Increased libido
  • Mood swings if testosterone levels get too high

SERIOUS SIDE EFFECTS ARE RARE BUT MAY INCLUDE:

•Allergic reactions characterized by difficulty in breathing, facial, lip, tongue, or throat swelling, and the appearance of hives. If any of these symptoms occur, promptly notify your clinician.

• Alterations in vision, including blurred vision or perception of light flashes.

• Chest pain, breathing difficulties, or leg swelling, which could be indicative of a blood clot. In the presence of any of these symptoms, it is crucial for you to promptly notify your clinician.

• Heightened risk of certain types of cancer, including breast cancer, endometrial cancer, ovarian cancer and prostate cancer. Enclomiphene exerts estrogenic effects making it unsuitable for members with a history of estrogen-sensitive cancers. If you have a history of these malignancies or a family history thereof, you should engage in a discussion with your clinician to assess your individual risks before considering enclomiphene treatment.

• Enclomiphene can also cause changes in liver function tests, particularly in patients with pre-existing liver disease. Patients with a history of liver problems should be monitored closely while taking enclomiphene, and may require dose adjustments or discontinuation of the medication if liver function tests become abnormal.

• Enclomiphene can cause changes in lipid levels, including increases in cholesterol and triglycerides. Patients with a history of high cholesterol or other lipid disorders should be monitored closely while taking enclomiphene, and may require additional treatment to manage these side effects.

CONTRAINDICATIONS

Enclomiphene is potentially contraindicated in patients who meet any of the following criteria:

Female sex (assigned at birth)
History of breast, endometrial (uterine), ovarian, or prostate cancer
History or pre-existing risk of blood clots
History of heart disease
Presence of current pituitary adenoma
History of liver disease
Uncontrolled adrenal or thyroid dysfunction
Known allergy to enclomiphene or clomiphene citrate
History of mania, bipolar disorder, or current manic symptoms (due to risk of mood swings)

If any of these contraindications apply to you, inform your clinician before starting treatment.

TREATMENT PROTOCOL

Your Healthcare Provider will determine the appropriate dosage of enclomiphene based on laboratory testing and medical history. The recommended starting dose is 6.25 mg by mouth daily. Most men feel symptomatic benefits within 2-4 weeks of starting the medication. If you have previously taken enclomiphene or are currently transitioning treatment of enclomiphene from another provider, they may be started at 12.5 mg or 25 mg, pending assessment from the clinician.

An increased dose of 12.5 mg or 25 mg by mouth daily may be indicated for some members not

experiencing symptomatic benefit. Symptoms and/or repeat labs will be reviewed with your clinician to determine the optimum dose and step-wise approach. Once your hormone levels and symptoms are optimized, you will be placed on a maintenance dose. Most men are on the protocol for at least 6-12 months and many continue for multiple years.

In order to continue receiving prescriptions, you will be required to complete laboratory testing before initiating treatment, three months after starting treatment, and then annually thereafter, unless otherwise indicated by your clinician in the event of a dose change or the occurrence of side effects.

USE OF TELEHEALTH

You understand that all Clinical Services will be provided via telehealth. Telehealth involves the delivery of healthcare services using electronic communications, information technology or other means between a healthcare provider and a patient who are not in the same physical location. Telehealth may be used for diagnosis, treatment, follow-up and/or patient education, and may include, but is not limited to, one or more of the following:

• Electronic transmission of client medical records, photo images, personal health information or other data between a patient and a provider;

• Interactions between a patient and provider via audio, video and/or data communications (such as messaging or email communications);

• Use of output data from medical devices, sound and video files.

• Alternative methods of care may be available to you, such as in-person services, and you may choose an alternative at any time.

Electronic systems used will incorporate network and software security protocols to protect the confidentiality of customer identification and imaging data and will include measures to safeguard the data and to ensure its integrity against intentional or unintentional corruption.

EXPECTED BENEFITS OF TELEHEALTH:

• Improved access to care by enabling a customer to remain at a remote site while consulting with practitioners at distant/other sites.

• More efficient client evaluation and management.

• Obtaining expertise of a distant specialist.

POSSIBLE RISKS OF TELEHEALTH

There are potential risks associated with the use of telehealth. These risks include, but may not be limited to:

• There is the potential that conditions that could be diagnosed with an in-person visit may go undetected in a remote encounter especially because a full physical exam cannot be performed

• In rare cases, information transmitted may not be sufficient (e.g. poor resolution of images) to allow for appropriate decision making by the Healthcare Provider;

• Delays in evaluation and treatment could occur due to deficiencies or failures of the equipment;

• In very rare instances, security protocols could fail, causing a breach of privacy of personal health information;

• In rare cases, a lack of access to complete health records may result in interactions or allergic reactions or other judgment errors.

Due to state licensure requirements for healthcare providers, you have to physically be in the state that your Healthcare Provider is licensed in during your telehealth visit. By agreeing to this Consent, you are confirming that you will only opt in to care when you are in your state of residence or in one of our locations. Furthermore, you are confirming that your state of residence is one in which the Medical Groups are licensed to treat.

PLEASE NOTE: THE MEDICAL GROUPS DO NOT ADDRESS MEDICAL EMERGENCIES. IF YOU BELIEVE YOU ARE EXPERIENCING A MEDICAL EMERGENCY, ARE CONSIDERING HARMING YOURSELF OR OTHERS, OR ARE OTHERWISE IN IMMINENT DANGER, YOU SHOULD DIAL 9-1-1 AND/OR GO TO THE NEAREST EMERGENCY ROOM.

You should seek emergency help or follow-up care when recommended by any healthcare provider or when otherwise needed. You should never discontinue medications or stop a course of treatment without first contacting your primary care provider or other medical professionals for advice. You should not delay treatment or advice from your primary care provider or other medical professionals based on information provided by the Healthcare Provider(s) via the Superpower Platform.

All laws and protections for in-person medical care also apply to telehealth care. This includes confidentiality of information, access to medical records, and sharing of information that could identify you personally. You may decide that you do not want to use the Clinical Services at any time, seek treatment elsewhere and/or with in-person offerings.

INFORMED CONSENT & ADHERENCE TO TREATMENT PLAN

Please sign below to acknowledge your understanding and agreement of the following terms in order to proceed with treatment with Enclomiphene therapy with a Medical Group Healthcare Provider via the Superpower Platform:

BY SIGNING THIS INFORMED CONSENT, YOU ACKNOWLEDGE THAT YOU HAVE READ AND UNDERSTAND THE INFORMATION PROVIDED ABOUT ENCLOMIPHENE TREATMENT, INCLUDING THE RISKS, BENEFITS, AND SAFETY CONSIDERATIONS. YOU AGREE TO ADHERE TO THE TREATMENT PROTOCOL AS PRESCRIBED BY YOUR HEALTHCARE PROVIDER AND TO REPORT ANY SEVERE SIDE EFFECTS OR CONCERNS TO YOUR HEALTHCARE PROVIDER PROMPTLY.

Take your medication exactly as directed and written on your prescription label. By FDA law, this medication is not for resale nor can it be returned for refund. Do not let anyone else take your medication. This medication is intended for use solely by the person for whom it is prescribed and should not be shared with any other individuals. Please follow the directions of your prescribing Healthcare Provider and on your prescription label carefully. If you need further explanation or have questions, please ask your prescribing Healthcare Provider to explain any part you do not understand.

You understand that the Healthcare Provider prescribing Enclomiphene holds a professional license issued by the professional licensing board or agency in the state where they practice. You can report a complaint relating to the care provided by contacting the appropriate state professional licensing board.

NO GUARANTEES:

You acknowledge that there are no guarantees or assurances made with respect to the results of taking the enclomiphene prescribed for you, and there are no guarantees that there will not be side effects and complications.

COMPLETE MEDICAL HISTORY:

You understand that Enclomiphene may be inappropriate and unsafe if you have certain health conditions, allergies, or take certain medications or supplements, whether prescribed or over-the-counter. For this and other reasons, you understand that it is vital that you truthfully and accurately disclose all health information requested by your prescribing Healthcare Provider including allergies, medications you are taking (both prescription and over the counter), medical/surgical/social/family history, and pertinent lab results, and keep your provider and your Patient Portal updated as to any changes in your health conditions and history during treatment with Enclomiphene, and you agree there shall be no liability on the part of the APNS, the providers or staff if you fail to do so.

BY CLICKING "I AGREE" AND PROVIDING YOUR ELECTRONIC SIGNATURE, YOU ARE PROVIDING YOUR INFORMED CONSENT TO RECEIVE ENCLOMIPHENE TREATMENT THROUGH THIS SERVICE. YOU CERTIFY THAT YOU ARE NOT CONSENTING ON BEHALF OF A MINOR CHILD, AS THIS SERVICE DOES NOT PROVIDE THIS TREATMENT TO INDIVIDUALS UNDER THE AGE OF 18.

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Signature Date

_____

Print Name

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