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To Hear or Not To Hear? A Pharmacist's Guide to OTC Hearing Aids

By Laura DiVirgilio, PharmD PGY-1
Big Y Community-Based Resident

Hearing loss affects nearly 20% of the world's population, over 5% of which will require rehabilitation for their hearing loss.[1] By 2050 it is estimated that one in every ten people will experience hearing loss that is disabling.[1] In adults, disabling hearing loss can lead to a number of issues including embarrassment, social isolation and loneliness, stigmatization, and prejudice. Furthermore, hearing loss can lead to depression and psychiatric disturbances as well as occupational stress and restricted career choices.[2]

Disabling hearing impairment is defined by the World Health Organization (WHO) as hearing loss greater than 25 decibels (dB) in the better hearing ear. Hearing loss may be mild, moderate, severe, or profound, and can affect one or both ears.[1] Regardless of the severity, hearing loss leads to a wide range of difficulty within conversational speech and can impact social situations, employment, and mental health. Although hearing impairment can be a significant burden, it is estimated that people wait an average of 10 years before pursuing the help they need for hearing loss.[3] While there are several barriers to hearing aid use including stigmatization and underestimation of hearing loss by the individual, one of the most common barriers is cost.[4]

On August 16, 2022, the Food and Drug Administration (FDA) issued a final rule approving over the counter (OTC) hearing aids for adults 18 years and older in the United States. This action enables those with mild to moderate hearing impairment to purchase hearing aids OTC. This means consumers may purchase a hearing aid online or in person at pharmacies and other retail stores with the goal of reducing the gap between those who could benefit from hearing aids and those who use them.[5] Pharmacists have the opportunity to provide crucial education and counseling to people seeking help for hearing impairment. It is imperative pharmacists are educated on proper hearing aid use, so they are fully prepared to triage patients and determine if they are suitable candidates for OTC hearing aids.

How to Screen for Suitable Candidates

To determine if a person meets the FDA approved indication for mild-moderate hearing loss, consider the following questions:

- Are you able to hear easily in quiet, one-on-one situations?
- Does turning up the volume on the phone or TV help you hear better? (Would this level be considered slightly loud to others as opposed to very loud and bothersome to others?)
- Would you use the OTC hearing aid in only a few difficult listening situations as opposed to needing it in most communication situations?

People who answer yes to these questions may have mild-moderate hearing loss and may be candidates for OTC hearing aids. People with more severe hearing loss may experience the same difficulties but to a greater degree, which is often identified by themselves or by others around them.[6]

How to Choose the Best OTC Hearing Aid

Several factors may impact an OTC hearing aid recommendation which include style, features, and cost. Hearing aids vary in style by size and the way they are placed in the ear. The completely in the canal (CIC) type hearing aid is the smallest and least visible type (see image A) and may be the best option for a patient who wants their hearing aid to be as discreet as possible. Disadvantages to this type include smaller batteries with shorter life and they typically do not come with extra features such as Bluetooth®, volume control, or a directional microphone.[7]

The receiver in canal (RIC) or receiver in the ear (RITE) styles (see image E) hook over the top of and rest behind the ear. It has a small wire connecting the piece behind the ear to a speaker that sits in the ear canal. This style may be more visible than the CIC type but has additional features such as directional microphones and manual control options for volume and power that may make RIC or RITE hearing aids the preferred options for some patients.[7]

For people that have mild to moderate high-frequency hearing loss (indicated by a difficulty understanding words that start or end in consonants like s, f, th, or t, or hearing is muffled in noisy environments or while watching TV), an open fit style may be best suitable (see image F).[7] An open fit style is often visible like RIC or RITE styles but doesn't plug the ear like the other in-the-ear hearing aid styles making it easier to hear one's own voice in conversation.

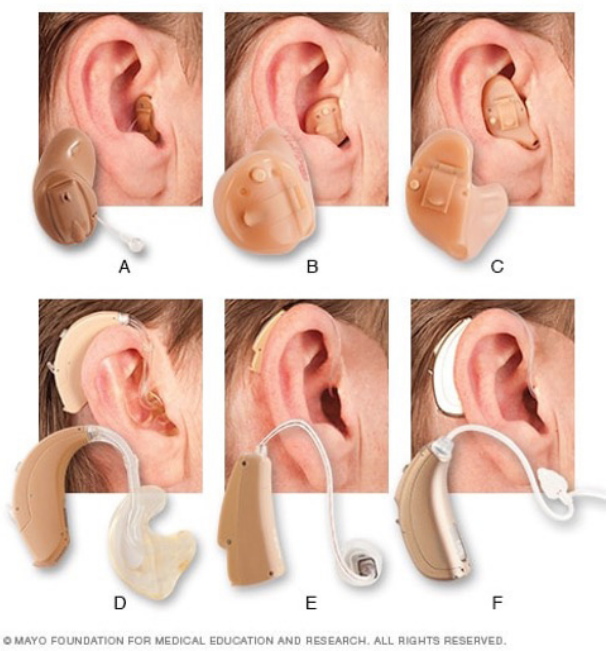

Figure 1: Types of Hearing Aids

Completely in the canal (A), in the canal (B), in the ear (C), behind the ear (D), receiver in canal or receiver in the ear (E), and open fit (F).

Other features to consider and discuss before making a hearing aid recommendation include noise reduction, directional microphones, rechargeable batteries, wireless connectivity, direct audio output which allows a patient to plug into audio from a device like a phone or TV with an additional cord, and synchronization for patients who have two hearing aids so any changes to volume will also be made on the other hearing aid.[7] Cost may be a determining factor when selecting the best hearing aid and is one of the advantages of OTC hearing aids. The cost of prescription hearing aids is estimated to be on average $4,600, but for some patients can reach upwards of $7,000 - $12,000 for premium devices.[8] OTC hearing aids on the other hand have more pricing options with hearing aids that range from less than $100 and can reach prices of up to $3,000 depending on the features.[8]

Patient Satisfaction and OTC Hearing Aid Safety

Dr. Tedeschi and Janette Kihm investigated participants' ability to self-identify the severity of their hearing loss, self-select a hearing device for their needs without the guidance of a professional, evaluate efficacy, and rate satisfaction with the use of an OTC hearing aid. Results revealed 15 of 30 patients were able to correctly identify their hearing loss as mild-to-moderate and 11 patients had hearing loss that was more severe than what they self-reported.[9] This study also demonstrated less than one-third of participants were familiar with the various features. Hearing aid style, price, and appearance were the factors most considered when selecting an OTC hearing aid and when given the options, many participants did not opt for the least expensive option, viewing price as an indicator of quality. At week 3 of the study, 38% of participants reported that they were satisfied with their hearing aid, with 28% neutral, and 34% dissatisfied. By week 6 of the study the percentage of satisfied participants increased to 48%, with 17% neutral, and 34% remained dissatisfied.

The satisfaction rate for specific listening situations was also evaluated and revealed that the OTC hearing aids appeared to work better when watching TV (satisfaction rate 75%), in conversations with small groups (satisfaction rate 68%), and one-on-one conversations (satisfaction rate 68%). This study also compared the satisfaction rates of professionally fitted hearing aids which had a satisfaction rate of 83%, with 11% neutral, and 6% dissatisfied.[9] Furthermore, this study noted that outcomes with OTC hearing aids appeared to be better when a hearing health care professional supported the users.[9]

While OTC hearing aids are expected to have many potential benefits, research is still limited. Studies occurring prior to the FDA approval of OTC hearing aids suggest that the electroacoustic characteristics of many devices vary drastically, with some devices producing dangerous output levels of over 120 decibels.[10,11] Now, with the new approval of OTC devices, the FDA is mandating an output limit of less than 111 decibels of sound pressure level addressing this concern.[12]

To assist in hearing aid selection, Table 1 is comprised of several OTC hearing aid options highly rated by a team of experts. These medical reviewers include audiologists, medical doctors, and board-certified geriatric nurse practitioners. Ratings are based off expert opinion, surveys from hearing aid users, and user reviews. Healthcare providers can utilize this table to narrow down the best OTC hearing aid option for patients based on several criteria, including style and price.[9]

The new FDA approval of OTC hearing aids will undoubtably alter the way millions of people with hearing loss seek treatment and purchase hearing aids.[13] As one of the most accessible healthcare professionals, pharmacists can expect to see an influx of questions about OTC hearing aids when purchasing these devices at the pharmacy. As a result, pharmacists should be familiar with popular OTC hearing aid options and their features to best aid in the selection of these devices to promote improved patient outcomes. This is evidenced by a National Survey of Pharmacist Awareness, Interest, and Readiness for Over-the-Counter Hearing Aids in which 54.55% of pharmacist respondents stated that they were "not at all familiar" with OTC hearing aids prior to the survey. On the other hand, 94.1% of respondents were somewhat or very interested in increasing their knowledge about OTC hearing aids.[13] Furthermore, 69.41% of respondents agreed or strongly agreed that patients in their community would purchase OTC hearing aids at a community pharmacy and 67.06% did not believe that they had the necessary knowledge to counsel patients on OTC hearing aids.[13] This survey puts into perspective the knowledge barrier that currently exists between pharmacists and their ability to recommend OTC hearing aids appropriately. Subsequently, it is imperative that pharmacists be knowledgeable about OTC hearing aid options and be able to make appropriate recommendations to enhance quality of life, promote hearing safety, and fill their role as a healthcare professional.

Table 1. Highest Expert-Rated OTC Hearing Aids:[8]

Hearing Aid	Style/Fit	Price	Rated
Audien™	In-the-canal	$99-$249	Most affordable
Jabra Enhance Plus™	In-the-ear	$799	Best Bluetooth compatibility
Lucid Hearing Engage	Behind-the-ear	$999	Best comfortable fit
Lexie Lumen	Behind-the-ear	$799	Best noise adaption & self-fitting
Lexie B2	Receiver-in-canal	$999	Best self-fitting
MDHearing™	Behind-the-ear	$299-$699	Best Rechargeable Hearing Aid for the price
Eargo™	In-the-ear	$1,450-$2,950	Best invisible fit

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Emergency Contraception: Now the Time is Ticking

Ji Yoon Kim
PharmD, PGY1 Community-Based Resident, Walgreens

On June 24, 2022, the United States Supreme Court issued its ruling on Dobbs v. Jackson Women's Health Organization and eliminated the constitutional right to abortion.[1] This ruling reversed Roe v. Wade, a landmark U.S. Supreme Court decision that established a constitutional right to abortion since 1973. Following the overturn, thirteen states enacted full bans on abortion with no exceptions for rape or incest, and five states enacted gestational limits on the procedure.[2] In the Commonwealth of Massachusetts, abortion is generally restricted at 24-weeks since last menstrual period.[3] Furthermore, if the patient is under the age of 16, one parent or guardian or a judge consent is required for the minor's abortion in Massachusetts.[3]

With the decreased access to abortion, concerns about the legal rights to contraception medications emerged. A few months after the Supreme Court decision, the U.S. Department of Health and Human Services issued an action plan to protect access to reproductive health care, including emergency contraception pills (ECP) and birth control coverage.[4,5] The Commonwealth of Massachusetts also took additional action to protect reproductive rights through House Bill 5090, An Act Expanding Protections for Reproductive and Gender-Affirming Care.[6] This bill provides legal protection to abortion providers, expanded access to contraceptives, including ECP, and helps to ensure that women who face grave circumstances after 24 weeks of pregnancy are not forced to leave Massachusetts to access reproductive health care services.[6]

According to the U.S. Centers for Disease Control and Prevention (CDC), 5.8 million or about 11% of sexually experienced women ages 15-49 used ECP in 2006-2010, and the percentage of sexually experienced women who have ever used ECP has increased since 1995.[7] In the most recent National Survey of Family Growth, the percentage of women ages 15-49 years who have ever had sexual intercourse and used ECP increased from 22% in 2015-2017 to 25.1% in 2017-2019.[8] As demand for ECP surges and the barriers to the use of ECP prevail, it is essential for health care providers to understand the indications, efficacy, and safety of ECPs available in the U.S. Currently, levonorgestrel and ulipristal acetate are the two Food and Drug Administration (FDA) approved ECPs.

Levonorgestrel is available as an oral tablet under various brand names, such as Plan B®, Plan B One-Step®, My Way®, and Next Choice®, and is also known as the morning-after pill. The FDA lifted the previous age requirement on Plan B® in 2013 and it has since been available as an over-the-counter medication regardless of age or gender.[9] These progestin-only products prevent pregnancy by several mechanisms.[10] The main mechanism of action is the prevention of ovulation. Through negative feedback of progesterone on the hypothalamus, a high dose of levonorgestrel reduces the secretions of follicle stimulating hormone (FSH) and luteinizing hormone (LH). If the follicle does not develop due to reduced levels of FSH, the follicle cannot release estradiol. The lack of estrogen's positive feedback further prevents the release of FSH and LH, and ovulation is prevented. High dose of levonorgestrel also alters the endometrium and cervical mucus thickness. Levonorgestrel will not prevent or interfere with the implantation of a fertilized egg.

Plan B® was the first prescription ECP approved in 1998. Because of the possible nonadherence to two doses of 0.75mg separated by 12 hours, Plan B One-Step® was approved in 2009 as a single dose of 1.5mg. Other levonorgestrel ECPs, including My Way® and Next Choice®, are also single doses of 1.5mg. A single dose regimen has been shown as noninferior compared to the two-dose regimen without increasing the risk of side effects.[11,12] For patients treated after 72 hours of unprotected intercourse, the risk of pregnancy (0.4% ≤72 h vs. 2.3% >72 h; p=0.0007) significantly increased compared to patients treated within 72 hours, regardless of a single-dose or two-dose levonorgestrel regimen.[13] Because of its mechanism of action, levonorgestrel is not effective as an emergency contraception once the implantation process has begun. Therefore, these ECPs should be taken as soon as possible within 72 hours of unprotected sexual intercourse or known or suspected contraceptive failure.

In addition to time from unprotected intercourse to treatment, body mass index (BMI) significantly impacts the risk of pregnancy when a patient is treated with levonorgestrel ECP. CDC defines BMI below 18.5 kg/m^2 as underweight, BMI between 18.5 kg/m^2 and 24.9 kg/m^2 as healthy weight, BMI between 25.0 kg/m^2 and 29.9 kg/m^2 as overweight, and BMI over 30.0 kg/m^2 as obesity.[14] In a meta-analysis of two randomized controlled trials, the risk of pregnancy was more than four times greater (OR, 4.41; 95% CI, 2.05–9.44; p=0.0002) for obese women and two times greater (OR, 2.06; 95% CI, 0.86–4.87; p>0.05) for overweight women in comparison with healthy weight or underweight women.[15] The randomized controlled trial further identified that levonorgestrel reached the limit of efficacy at a weight of 70 kg, or 156 lb, and this risk factor was statistically significant (p<0.0001).[15] BMI and weight, as they relate to ECP effectiveness, are important counseling points for patients to avoid increased failure rates.

Ulipristal acetate, an oral tablet available as the brand name ella®, was approved in 2010 as an ECP with a unique mechanism of action. It is a selective progesterone receptor modulator, which prevents progestin from binding to the progesterone receptor. When administered prior to ovulation, ulipristal postpones follicular rupture which leads to delay or inhibition of ovulation. Ulipristal also alters the endometrium. The dose approved for emergency contraceptive is a single dose of 30mg. Unlike levonorgestrel, ulipristal requires a prescription regardless of age.

In an international randomized controlled trial, the use of ulipristal demonstrated noninferiority compared to single-dose levonorgestrel as an emergency contraceptive in women receiving treatment within 72 hours of unprotected sexual intercourse.[11] In the study, participants who received emergency contraception between 72 hours and 120 hours after sexual intercourse, prevented significantly more pregnancies with ulipristal than with levonorgestrel (p=0.037).[12] Another study compared the efficacy of ulipristal in women presenting 48 to 72 hours, 72 to 96 hours, and 96 to 120 hours after unprotected intercourse, and efficacy did not decrease over time.[16] Because of its mechanism of action, ulipristal is effective as an emergency contraception prior to ovulation whereas levonorgestrel is not effective once the implantation process begins. Therefore, these ECPs can be taken up to 120 hours after unprotected sexual intercourse or known or suspected contraceptive failure.

BMI and weight can impact the risk of pregnancy when patients are treated with ulipristal or levonorgestrel. Unlike levonorgestrel that showed a rapid decrease of efficacy with increasing BMI, the relative risk of becoming pregnant in patients treated with ulipristal was not different in overweight patients (BMI 25.0 kg/m^2 - 29.9 kg/m^2) compared to those with normal or underweight BMI.[15] However, another study found a two-fold increase in the risk of pregnancy among obese women with BMI greater than 30 kg/m^2 compared with nonobese women (OR, 8.27; 95% CI, 2.70–25.37) when treated with ulipristal.[17] Ulipristal also reached the limit of efficacy at 88 kg, or 164 lb. The CDC reports that the average American woman over the age of 20 weighs approximately 77.6 kg or 170.8 lb.[18] Therefore, millions of American women may be risk of ECP treatment failure with levonorgestrel and some with ulipristal.

There are several factors to consider when making recommendations for ECP based on previous studies on the efficacy of levonorgestrel and ulipristal. To help with this decision, Table 1 outlines ECP recommendations based on various patient scenarios. Additionally, Table 2 provides common counseling points for ECP, as well as specific counseling points for levonorgestrel and ulipristal. These resources can help make informed recommendations tailored to meet patient's needs.

Prescription requirements for ECP can be a barrier for women looking to use ECP after sexual intercourse to prevent an unintended pregnancy. Several states including Massachusetts, Maine, New Hampshire, California, Hawaii, New Mexico, and Washington allow pharmacists to directly prescribe ECP to women of all ages.[19] In August 2022, the Commonwealth of Massachusetts and the Massachusetts Department of Public Health issued a standing order for dispensing ECP as part of the 2022 Act Expanding Protections for Reproductive and Gender-Affirming Care.[20] The statewide standing order is for all retail pharmacies to voluntarily dispense levonorgestrel and ulipristal, to women of all reproductive ages. In combination with the 2017 Act Relative to Advancing Contraceptive Coverage and Economic Security in Our State (ACCESS), patients can get ECP at no cost if they are on a fully-insured health plan.[21] Fully-insured health plans, including MassHealth and plans through the MA Group Insurance Commission, are group health plans where an employer buys health insurance for their employees through a commercial insurer. These policies allow patients to use ECP in a timely manner at no cost.

ECPs are an important contraceptive option that can prevent unintended pregnancies when used correctly and in a timely manner. Due to the elimination of the constitutional right to abortion, there are concerns about the legal rights to contraception medications, including ECP. Levonorgestrel and ulipristal acetate are the two FDA-approved ECPs available in the U.S. with different mechanisms of action and recommended doses. Time of administration after unprotected sexual intercourse or known or suspected contraceptive failure and BMI are two factors that significantly impact the risk of pregnancy. Therefore, it is essential for healthcare providers to understand the indications, efficacy, and safety of ECPs. By doing so, healthcare providers can promote reproductive health and empower individuals to make informed choices about their bodies and lives.

For MA physicians, nurse practitioners, physician assistants, and pharmacists, there is an online course offering 2.5 continuing education (CE) credits about the ACCESS law. This free CE course is found at learnmore.mghihp.edu/ACCESS. More information about the Standing Order for Dispensing Emergency Contraception Pills can be found at www.mass.gov/doc/standing-order-for-dispensing-emergency-contraception-pills/download.

Table 1. Counseling Points for ECPs[22,23,25]	
Common Counseling Points	• Do not use this medication if you are pregnant. • If you vomit within two to three hours of taking this medication, call your healthcare provider right away. Your provider may prescribe another dose to repeat and an anti-nausea medication if appropriate. • This medication is only for occasional use as emergency birth control. It should not replace your regular birth control method. • Some foods and medications can affect how the medication works. Tell your prescriber if you are using carbamazepine, oxcarbazepine, phenytoin, rifampin, topiramate, St John's wort, barbiturate, ketoconazole, or itraconazole. • Store the medication in a closed container at room temperature, away from heat, moisture, and direct light. Keep the tablet in the blister card inside the original box until you are ready to use it. Do not use it if the package is broken or torn. • This medication will not protect you from HIV/AIDS or other sexually transmitted infections. • Contact your primary care provider, reproductive health provider, or family planning clinic for follow up.

Levonorgestrel (Plan B One-Step®)	• Do not use this medication if you had an allergic reaction to levonorgestrel or to other progestin drugs, such as norethindrone oral contraceptives (Camila®, Errin®, Jolivette®, Ovrette®, Lyza®, Nor-QD®, Nora-BE®, Otho Micronor®), progesterone, megestrol, or medroxyprogesterone. Allergic reactions may appear as itching or hives, swelling in your face or hands, swelling, or tingling in your mouth or throat, chest tightness, trouble breathing. • Take one 1.5mg tablet as soon as possible within three days (72 hours) after unprotected sex or failure of another birth control method. • Possible side effects while using this medication include heavier menstrual bleeding, nausea, lower abdominal pain, fatigue, headache, dizziness, or breast tenderness. • You may have spotting a few days after using this medication. With your next period, you may bleed a little more or a little less than usual. • After using this medication, you should have your next period at the expected time. If your next period is more than one week late, take a pregnancy test. • Your regular hormonal birth control method can be initiated or resumed immediately after taking this medication, with use of a reliable barrier method for seven days.
Ulipristal (ella®)	• Do not use this medication if you had an allergic reaction to ulipristal. Allergic reactions may appear as itching or hives, swelling in your face or hands, swelling, or tingling in your mouth or throat, chest tightness, trouble breathing. • Take one tablet as soon as possible within five days (120 hours) after unprotected sex or failure of another birth control method.
	• Possible side effects while using this medication include headache, mild pain with your next period or light spotting before your period starts, nausea, mild stomach pain, tiredness, or dizziness. • This medication may make your next monthly period early or late by a few days. If your next period is more than one week late, take a pregnancy test. • Your regular birth control method including birth control pills, vaginal ring, or patch may not work as well while you are using this medication. Do not start taking a hormonal contraceptive for at least five days after you take this medication. Abstain from sexual intercourse or use a reliable barrier method for the next seven days or until your next period, whichever comes first.

Table 2. ECP Recommendations Based on Various Scenarios[11,12,13,14,15,16,17,24,25]		
Scenario	Recommendation for ECP	Alternative and Rationale
0-72 hours since unprotected sex	Levonorgestrel or Ulipristal	
73-120 hours since unprotected sex	Ulipristal	Levonorgestrel efficacy may be decreased but could be used if Ulipristal not available
Weight ≤ 156 lb or BMI ≤ 26 kg/m²	Levonorgestrel or Ulipristal	
Weight > 156 lb or BMI > 26 kg/m²	Ulipristal	Levonorgestrel efficacy may be decreased but could be used if Ulipristal not available
Breastfeeding	Levonorgestrel	If using Ulipristal, delay breastfeeding for 24 hours
Need to start or restart hormonal contraception immediately	Levonorgestrel	If using Ulipristal, delay hormonal contraception at least 5 days

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